

US3222143 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:03:40

All time stamps listed in this document are displayed in GMT

US3222143

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

[Participant ID](#)

US3222143

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

US3222143

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Date of Birth (MMM yyyy)	(b) (6) 1983
Age	37
Age Units	YEARS
Age (Derived)	37
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 17:33:05

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Date of Informed Consent (<i>dd MMM yyyy</i>)	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" 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 17:33:05

Generated On: 09 Jun 2021 16:03:40

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 17:33:05

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Condition	ANXIETY
Start date (dd MMM yyyy)	01 JAN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Condition	CARPAL TUNNEL SURGERY- RIGHT WRIST
Start date (dd MMM yyyy)	01 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JAN 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	01 JAN 2012
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)	01 JAN 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3222143

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Condition	CYST REMOVED- RIGHT WRIST
Start date (dd MMM yyyy)	01 JAN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JAN 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	01 JAN 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222143

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Condition	LAPAROSCOPY
Start date (dd MMM yyyy)	01 JAN 2013
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)	01 JAN 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Condition	ENDOMETRIAL CYSTS - BENIGN
Start date (dd MMM yyyy)	01 JAN 2013
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)	01 JAN 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:40
Height (<i>xxx.x</i>)	162.6 cm
Weight (<i>xxx.x</i>)	94.1 kg
BMI (<i>xxx.x</i>)	35.59168 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 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*) 14 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 14 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:33:09

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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

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 17:33:09

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 103978

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 ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

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)	14 AUG 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:40
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 11:45 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 11:45

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	11:18 (24 HR)
Collection date and time (derived)	14 AUG 2020 11:18

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:22	14 AUG 2020 11:22
Nasopharyngeal Swab 2	No		

US3222143

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 14 AUG 2020 12:15

PC Open Date & Time 14 AUG 2020 12:05

PC Close Date & Time 14 AUG 2020 14:35

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

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 14 AUG 2020 15:30

PC Close Date & Time 15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 20:53

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

97.2 °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

17 AUG 2020 15:30

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

18 AUG 2020 14:23

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

97.2 °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

19 AUG 2020 12:39

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

97.4 °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

20 AUG 2020 12:39

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

14 AUG 2020 12:15

PC Open Date & Time

14 AUG 2020 12:05

PC Close Date & Time

14 AUG 2020 14:35

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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 ☐

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.**

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

PC Open Date & Time

14 AUG 2020 15:30

PC Close Date & Time

15 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

15 AUG 2020 12:33

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

16 AUG 2020 20:53

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

17 AUG 2020 15:31

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

18 AUG 2020 14:23

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

19 AUG 2020 12:40

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

20 AUG 2020 12:39

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 12:16
PC Open Date & Time	14 AUG 2020 12:05
PC Close Date & Time	14 AUG 2020 14:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 AUG 2020 15:30

PC Close Date & Time

15 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

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 ☒

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:33
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

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 ☒

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:53
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

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 ☒

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EAB) (1725)

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US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 15:31
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

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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US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 14:24
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

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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US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:41
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

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 ☒

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:40
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3222143

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

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)	16 SEP 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:45
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:11
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3222143

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	16 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 13:40 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 13:40

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

US3222143

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

13:26 (24 HR)

Collection date and time (derived)

16 SEP 2020 13:26

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:30	16 SEP 2020 13:30
Nasopharyngeal Swab 2	No		

US3222143

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 14:06

PC Open Date & Time

16 SEP 2020 14:00

PC Close Date & Time

16 SEP 2020 16:30

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

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

16 SEP 2020 17:25

PC Close Date & Time

17 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	17 SEP 2020 13:43
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	18 SEP 2020 16:50
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

96.4 °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

19 SEP 2020 17:26

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 14:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

21 SEP 2020 21:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 21:33

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

16 SEP 2020 14:05

PC Open Date & Time

16 SEP 2020 14:00

PC Close Date & Time

16 SEP 2020 16:30

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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 ☐

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.**

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

PC Open Date & Time

16 SEP 2020 17:25

PC Close Date & Time

17 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

17 SEP 2020 13:43

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

18 SEP 2020 16:51

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

19 SEP 2020 17:26

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

20 SEP 2020 14:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

21 SEP 2020 21:01

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

22 SEP 2020 21:33

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 14:06
PC Open Date & Time	16 SEP 2020 14:00
PC Close Date & Time	16 SEP 2020 16:30

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 17:25

PC Close Date & Time

17 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

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 ☒

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 13:44
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

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)

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 16:51
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

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 ☒

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 17:27
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 14:20
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

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)

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 21:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 21:33
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3222143

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222143

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

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.

US3222143

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

10:09 (24 HR)

Collection date and time (derived)

15 OCT 2020 10:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:09

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 09:16:59

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 06:05:25

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 21:17:51

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 23:19:26

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 11:55:15

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 DEC 2020 13:35:09
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 DEC 2020 08:34:28
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 12:52:42

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 10:58:30

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 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	03 JAN 2021 21:35:29
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

11 JAN 2021 22:02:51

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

20 JAN 2021 13:54:17

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 21:02:58

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

09 FEB 2021 13:56:31

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

16 FEB 2021 08:21:49

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 12:47:36

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

10 MAR 2021 20:50:46

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

16 MAR 2021 10:07:58

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

24 MAR 2021 09:37:41

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 18:58:55

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

07 APR 2021 21:51:18

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

13 APR 2021 10:42:18

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 <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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

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03 FEB 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

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10 FEB 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

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03 MAR 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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°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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

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31 MAR 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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°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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3222143

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:03:40

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		05 MAR 2021 16:14:33

US3222143

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:18:52

Generated On: 09 Jun 2021 16:03:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222143

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:18:52

Generated On: 09 Jun 2021 16:03:40

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.

US3222143

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:18:52

Generated On: 09 Jun 2021 16:03:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 MAR 2021
Collection time (00:00-23:59)	11:00 (24 HR)
Collection date and time (derived)	10 MAR 2021 11:00

US3222143

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:18:52

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222143

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222143

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222143

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:03:40

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"/>

US3222143

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:03:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222143

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID UNBLND_DECIDE

US3222143

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Date of updated informed consent (<i>dd MMM yyyy</i>)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	18 DEC 2020
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3222143

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3222143

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:40

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

US3222143

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

AEID	USA-US104-2020-MRNA-1273-P30 1000026
Adverse event	LUNG NODULES BENIGN
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)	11 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	12 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	DIAGNOSED WITH UNCLASSIFIED LUNG NODULES.
Narrative	THE PATIENT WAS CALLED AFTER RECEIVING AN E-DIARY ALERT. I SPOKE WITH HER TODAY AT 08:40 AM. SHE WAS ADMITTED TO THE ER FOR SHORTNESS OF BREATH. THEY DID A CHEST CT AND FOUND NODULES. I WILL REQUEST MEDICAL RECORDS..

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 22:12:54

Generated On: 09 Jun 2021 16:03:40

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

Yes ☒

No ☐

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

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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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US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

	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 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Name of Medication AMITRIPTYLINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Name of Medication LOESTRIN

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 1944

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

	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 2018	
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"/>

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication VACCINE

Dose per administration 0.5

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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US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:49:50

Generated On: 09 Jun 2021 16:03:40

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3222143

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 17:33:05

Generated On: 09 Jun 2021 16:03:40

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3222143

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:03:40

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

US3222143

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:03:40

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 ☐

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:12:54

Generated On: 09 Jun 2021 16:03:40

SAEID	USA-US104-2020-MRNA-1273-P301000026
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:12:54

Generated On: 09 Jun 2021 16:03:40

SAEID	USA-US104-2020-MRNA-1273-P301000026
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/DEC/2020 06:27
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

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:12:54

Generated On: 09 Jun 2021 16:03:40

SAEID	USA-US104-2020-MRNA-1273-P301000026
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/MAR/2021 09:29
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

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:12:54

Generated On: 09 Jun 2021 16:03:40

SAEID	USA-US104-2020-MRNA-1273-P301000026
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/APR/2021 11:54
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

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:12:54

Generated On: 09 Jun 2021 16:03:40

SAEID	USA-US104-2020-MRNA-1273-P301000026
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 13:27
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

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:12:54

Generated On: 09 Jun 2021 16:03:40

SAEID	USA-US104-2020-MRNA-1273-P301000026
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/APR/2021 15:30
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

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 22:12:54

Generated On: 09 Jun 2021 16:03:40

SAEID	USA-US104-2020-MRNA-1273-P301000026
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	27/APR/2021 11:21
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

US3222143 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222143

Form: Participant Creation

Generated On: 09 Jun 2021 16:03:40

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'US3222143'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:14:22

US3222143

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:24

US3222143

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:14:22

US3222143

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:24

US3222143

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User entered 'SCRN'	System	14 Aug 2020 15:54:24

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered (b) (6) 1983' reason for change: Data Entry Error	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 04:44:18
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:14:23

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	16 Sep 2020 18:45:59
User entered '37' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Sep 2020 18:45:59
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	16 Sep 2020 04:44:18
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	14 Aug 2020 19:41:44
User entered '35' reason for change: Data Entry Error	Crystal Paccione (b) (4)	14 Aug 2020 19:41:44
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	14 Aug 2020 19:41:36
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	14 Aug 2020 19:41:36
User entered '36' reason for change: Data Entry Error	Crystal Paccione (b) (4)	14 Aug 2020 19:41:36
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	14 Aug 2020 19:41:22
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	14 Aug 2020 19:41:22
User entered '39' reason for change: Data Entry Error	Crystal Paccione (b) (4)	14 Aug 2020 19:41:22
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	14 Aug 2020 19:41:17
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	14 Aug 2020 19:41:17
User entered '38' reason for change: Data Entry Error	Crystal Paccione (b) (4)	14 Aug 2020 19:41:17
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	14 Aug 2020 19:41:00
User entered '37'	Crystal Paccione (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'YEARS'	System	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '37'	System	16 Sep 2020 04:44:18
User entered '35'	System	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Female (F)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'I'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:40

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:41:00

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '14 Aug 2020'	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Aug 2020'	System	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2020'	System	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Amendment 2 (2)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:35

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:14:22

US3222143

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'I'	System	14 Aug 2020 15:54:41

US3222143

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:03:40

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:54:41

US3222143

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:03:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:34:10

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:03:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:03:51
Data point term sent to Coder	System	14 Aug 2020 19:35:15
User entered 'Anxiety'	Crystal Paccione (b) (4)	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2010'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2010'	System	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2010'	System	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered empty.	System	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:40

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered empty.	System	14 Aug 2020 19:34:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:02:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:02:53
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 17:33:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel decompression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:40
Data point term sent to Coder	System	14 Aug 2020 19:36:19
User entered 'Carpal Tunnel Surgery- right wrist'	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2014'	Crystal Paccione (b) (4)	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2014'	Crystal Paccione (b) (4)	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2014'	System	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2014'	System	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2014'	System	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:40

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2014'	System	14 Aug 2020 19:35:32

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:04:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:04:32
Data point term sent to Coder	System	14 Aug 2020 19:36:20
User entered 'Cesarean Section'	Crystal Paccione (b) (4)	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2012'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2012'	Crystal Paccione (b) (4)	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2012'	System	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2012'	System	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2012'	System	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:40

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2012'	System	14 Aug 2020 19:36:08

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 09:01:34
User opened query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. 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)	10 Sep 2020 09:01:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cyst removal, LLT: Cyst removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:20:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:20:27
Data point term sent to Coder	System	14 Aug 2020 19:37:24
User entered 'CYST REMOVED- right wrist' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:36:57
User entered 'Cyst removed'	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2010'	Crystal Paccione (b) (4)	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2010'	Crystal Paccione (b) (4)	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2010'	System	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2010'	System	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2010'	System	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:40

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2010'	System	14 Aug 2020 19:36:44

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:06:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:06:44
Data point term sent to Coder	System	14 Aug 2020 19:38:25
User entered 'Endometriosis'	Crystal Paccione (b) (4)	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2011'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2011'	System	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2011'	System	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered empty.	System	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:40

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered empty.	System	14 Aug 2020 19:38:04

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:40:32
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	23 Sep 2020 13:53:44
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 09:04:47
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Laparoscopy, LLT: Laparoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:07:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:07:29
Data point term sent to Coder	System	14 Aug 2020 19:40:43
User entered 'Laparoscopy'	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2013'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2013'	Crystal Paccione (b) (4)	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2013'	System	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2013'	System	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2013'	System	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:40

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2013'	System	14 Aug 2020 19:40:26

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User closed query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 19:15:14
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometrial disorder, LLT: Endometrium cystic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 00:29:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 00:29:29
Data point term sent to Coder	System	21 Oct 2020 19:28:07
Query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. 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).	(b) (4), (b) (6)	21 Oct 2020 19:27:55
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 19:27:35
User entered 'ENDOMETRIAL CYSTS - benign' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:27:35
User opened query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 16:57:01
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometrial disorder, LLT: Endometrium cystic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:08:43

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	23 Sep 2020 15:08:43 23 Sep 2020 13:54:04
User entered 'ENDOMETRIAL CYSTS'	Albert Garcia (b) (4) (b) (4)	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2013'	Albert Garcia (b) (4)	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Albert Garcia (b) (4)	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'No (N)'	Albert Garcia (b) (4)	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '01 Jan 2013'	Albert Garcia (b) (4)	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Albert Garcia (b) (4)	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2013'	System	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2013'	System	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered 'Jan 2013'	System	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:03:40

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered '2013'	System	23 Sep 2020 13:53:19

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 Aug 2020'	Crystal Paccione (b) (4)	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '10:40'	Crystal Paccione (b) (4)	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User entered '14 Aug 2020 10:40'	System	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '162.6' cm	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:33:41
DataPoint set to visible.	(b) (4) System	14 Aug 2020 15:54:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '94.1' kg	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:33:41
DataPoint set to visible.	(b) (4) System	14 Aug 2020 15:54:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
Amendment Manager: User entered '35.59168'	System	16 Sep 2020 23:57:07
User entered '35.6'	System	14 Aug 2020 19:33:41
DataPoint set to visible.	System	14 Aug 2020 15:54:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User entered 'kg/m2'	System	14 Aug 2020 19:33:41
DataPoint set to visible.	System	14 Aug 2020 15:54:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:31:59
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'Updated' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:21:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:21:12
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:56:19
User entered '36.5' C	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	16 Sep 2020 19:21:12
	(b) (4)	
User entered 'Oral (Oral)'	Crystal Paccione (b) (4)	14 Aug 2020 19:33:41
	(b) (4)	

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 19:21:12
User entered '70'	Albert Garcia (b) (4)	16 Sep 2020 19:21:12
	(b) (4)	
	Crystal Paccione (b) (4)	14 Aug 2020 19:33:41
	(b) (4)	

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User entered 'bpm'	System	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 19:21:12
User entered '16'	Albert Garcia (b) (4)	16 Sep 2020 19:21:12
	(b) (4)	
	Crystal Paccione (b) (4)	14 Aug 2020 19:33:41
	(b) (4)	

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User entered 'breaths/min'	System	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 19:21:12
User entered '108'	Albert Garcia (b) (4)	16 Sep 2020 19:21:12
	(b) (4)	
	Crystal Paccione (b) (4)	14 Aug 2020 19:33:41
	(b) (4)	

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User entered 'mmHg'	System	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 19:21:12
User entered '80'	Albert Garcia (b) (4)	16 Sep 2020 19:21:12
	(b) (4)	
	Crystal Paccione (b) (4)	14 Aug 2020 19:33:41
	(b) (4)	

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User entered 'mmHg'	System	14 Aug 2020 19:33:41

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47

US3222143

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47

US3222143

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:32:36

US3222143

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	18 Sep 2020 18:56:29
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:56:29
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:56:29
User entered '14 Aug 2020' reason for change: Data Entry Error	douglas winter (b) (4)	18 Sep 2020 18:56:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:56:25
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	18 Sep 2020 18:56:25
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:56:25
User entered '14 Apr 2020' reason for change: Data Entry Error	douglas winter (b) (4)	18 Sep 2020 18:56:25
Comment added 'PE IS NOT PRIOR. PLEASE REMOVE QUERY'.	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	Albert Garcia (b) (4)	17 Sep 2020 20:35:09
User entered '14 Aug 2020'	(b) (4)	
	System	16 Sep 2020 17:56:54
	Crystal Paccione (b) (4)	14 Aug 2020 19:32:36
	(b) (4)	

US3222143

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '14 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:42:57

US3222143

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:40

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:42:57

US3222143

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:40

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:42:57

US3222143

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:40

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:42:57

US3222143

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:40

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:42:57

US3222143

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:40

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	Crystal Paccione (b) (4)	14 Aug 2020 19:42:57

US3222143

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:40

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:42:57

US3222143

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:40

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '0'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:42:57

US3222143

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Albert Garcia (b) (4)	23 Sep 2020 13:51:24

US3222143

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '14 Aug 2020'	Albert Garcia (b) (4)	23 Sep 2020 13:51:24

US3222143

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Urine (URINE)'	Albert Garcia (b) (4)	23 Sep 2020 13:51:24

US3222143

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Negative (NEGATIVE)'	Albert Garcia (b) (4)	23 Sep 2020 13:51:24

US3222143

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'No (N)'	Albert Garcia (b) (4)	23 Sep 2020 13:51:24

US3222143

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	Albert Garcia (b) (4)	23 Sep 2020 13:51:24

US3222143

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	Albert Garcia (b) (4)	23 Sep 2020 13:51:24

US3222143

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:43
User entered empty.	System	23 Sep 2020 13:51:24

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '0'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '0'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '0'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '0'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

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 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '0'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'I'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '0'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:04:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:15

US3222143

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:24

US3222143

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 Aug 2020'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:24

US3222143

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:24

US3222143

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'VISIT1'	System	14 Aug 2020 15:55:24

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:29:35

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:31:18
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:31:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 15:29:35
User entered '103978' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:29:35

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:29:35

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

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)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:36

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

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)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:36

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:36

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:36

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:55:36

US3222143

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:40

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Albert Garcia (b) (4)	23 Sep 2020 13:51:35
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:16:41

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User closed query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:23:17
Query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' answered with 'Updated' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:13
User opened query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:37
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:37
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:51
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:04:55
User entered '162.6' cm reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:53
User entered empty.	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:40

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User closed query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:23:20
Query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' answered with 'Updated' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:13
User opened query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:42
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:42
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:59
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:05:05
User entered '84.1' kg reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:53
User entered empty.	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User closed query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:23:17
Query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' answered with 'Updated' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:13
User opened query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:37
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:37
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:51
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:04:55
User entered '162.6' cm reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:53
User entered empty.	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:40

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User closed query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:23:20
Query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' answered with 'Updated' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:13
User opened query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:42
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:42
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:59
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:05:05
User entered '84.1' kg reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:53
User entered empty.	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User accepted default value 'Pre-Dose (PREDOSE)'	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '10:40'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '14 Aug 2020 10:40'	System	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '36.5' C	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '70'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'bpm'	System	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'breaths/min'	System	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '108'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'mmHg'	System	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '80'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'mmHg'	System	14 Aug 2020 19:31:30

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User closed query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:23:17
Query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' answered with 'Updated' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:13
User opened query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:37
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:37
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:51
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:04:55
User entered '162.6' cm reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:53
User entered empty.	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:40

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User closed query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:23:20
Query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' answered with 'Updated' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:22:13
User opened query 'Per CDM: Re-query: Kindly enter "ND" in the text fields. Please update appropriately.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:42
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 19:12:42
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:59
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 22:26:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:05:05
User entered '84.1' kg reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:31:53
User entered empty.	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User accepted default value 'Post-Dose (POSTDOSE)'	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
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) (4), (b) (6)	18 Aug 2020 12:31:05
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol correct' (Site from System).	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:32:12
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 19:30:22
User entered '12:15'	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '14 Aug 2020 12:15'	System	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '36.7' C	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '72'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'bpm'	System	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'breaths/min'	System	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '106'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'mmHg'	System	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '80'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'mmHg'	System	14 Aug 2020 19:30:22

US3222143

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:28:47

US3222143

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:28:47

US3222143

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4)	23 Sep 2020 13:51:58
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	15 Aug 2020 18:05:48

US3222143

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	23 Sep 2020 13:51:58
User entered '14 Aug 2020'	Alicia Cevera (b) (4)	15 Aug 2020 18:05:48

US3222143

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty; reason for change Data Entry Error	(b) (4)	23 Sep 2020 13:51:58
User entered 'Urine (URINE)'	Albert Garcia (b) (4)	15 Aug 2020 18:05:48
	(b) (4)	

US3222143

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	23 Sep 2020 13:51:58
User entered 'Negative (NEGATIVE)'	Alicia Cevera (b) (4)	15 Aug 2020 18:05:48

US3222143

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	23 Sep 2020 13:51:58
User entered 'No (N)'	Alicia Cevera (b) (4)	15 Aug 2020 18:05:48

US3222143

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Aug 2020 18:05:48

US3222143

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Aug 2020 18:05:48

US3222143

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	15 Aug 2020 18:05:48

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Jennifer Dittman (b) (4)	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

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)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Jennifer Dittman (b) (4)	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 Aug 2020'	Jennifer Dittman (b) (4)	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '11:45'	Jennifer Dittman (b) (4)	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '14 Aug 2020 11:45'	System	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'ONCE'	System	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 15:56:13

US3222143

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:27:00

US3222143

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:27:00

US3222143

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '11:18'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:27:00

US3222143

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '14 Aug 2020 11:18'	System	14 Aug 2020 19:27:00

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:03:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '11:22'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '14 Aug 2020 11:22'	System	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Crystal Paccione (b) (4)	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	14 Aug 2020 19:26:36

US3222143

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	14 Aug 2020 19:24:27

US3222143

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	14 Aug 2020 19:24:27

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:24', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6e2c4528-51c6-44ee-ac47-77543eb6677c' User entered 'Yes (Y)'	System	14 Aug 2020 16:15:40
	System	14 Aug 2020 16:15:40

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:32', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6e2c4528-51c6-44ee-ac47-77543eb6677c' User entered '98.0'	System	14 Aug 2020 16:15:40
	System	14 Aug 2020 16:15:40

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:34', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6e2c4528-51c6-44ee-ac47-77543eb6677c' User entered 'No (N)'	System	14 Aug 2020 16:15:40
	System	14 Aug 2020 16:15:40

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:38', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6e2c4528-51c6-44ee-ac47-77543eb6677c'	System	14 Aug 2020 16:15:40
User entered '14 Aug 2020 12:15'	System	14 Aug 2020 16:15:40

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 12:05'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 14:35'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 15:30'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 2'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:32:37', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a4011b27-ebdd-4d42-8595-ca7fe42141c4' User entered 'Yes (Y)'	System	15 Aug 2020 16:32:48
	System	15 Aug 2020 16:32:48

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:32:41', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a4011b27-ebdd-4d42-8595-ca7fe42141c4' User entered '97.5'	System	15 Aug 2020 16:32:48
	System	15 Aug 2020 16:32:48

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:32:44', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a4011b27-ebdd-4d42-8595-ca7fe42141c4'	System	15 Aug 2020 16:32:48
User entered 'No (N)'	System	15 Aug 2020 16:32:48

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:32:46', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a4011b27-ebdd-4d42-8595-ca7fe42141c4' User entered '15 Aug 2020 12:32'	System	15 Aug 2020 16:32:48
	System	15 Aug 2020 16:32:48

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 3'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:52:49', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3f245a99-e0f2-4f25-81d8-feae913f70eb' User entered 'Yes (Y)'	System	17 Aug 2020 00:53:03
	System	17 Aug 2020 00:53:03

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:52:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3f245a99-e0f2-4f25-81d8-feae913f70eb' User entered '97.8'	System	17 Aug 2020 00:53:03
	System	17 Aug 2020 00:53:03

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:52:57', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3f245a99-e0f2-4f25-81d8-feae913f70eb'	System	17 Aug 2020 00:53:03
User entered 'No (N)'	System	17 Aug 2020 00:53:03

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3f245a99-e0f2-4f25-81d8-feae913f70eb' User entered '16 Aug 2020 20:53'	System	17 Aug 2020 00:53:03
	System	17 Aug 2020 00:53:03

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 4'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:30:46', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e3dce676-3dff-40b6-b73b-1242ce03c494' User entered 'Yes (Y)'	System	17 Aug 2020 19:30:59
	System	17 Aug 2020 19:30:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:30:50', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e3dce676-3dff-40b6-b73b-1242ce03c494' User entered '97.2'	System	17 Aug 2020 19:30:59
	System	17 Aug 2020 19:30:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:30:52', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e3dce676-3dff-40b6-b73b-1242ce03c494'	System	17 Aug 2020 19:30:59
User entered 'No (N)'	System	17 Aug 2020 19:30:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:30:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e3dce676-3dff-40b6-b73b-1242ce03c494'	System	17 Aug 2020 19:30:59
User entered '17 Aug 2020 15:30'	System	17 Aug 2020 19:30:59

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 5'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:15', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'df8cfb3c-2aa8-4c57-b21a-4a13950c3961' User entered 'Yes (Y)'	System	18 Aug 2020 18:23:34
	System	18 Aug 2020 18:23:34

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:22', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'df8cfb3c-2aa8-4c57-b21a-4a13950c3961' User entered '97.1'	System	18 Aug 2020 18:23:34
	System	18 Aug 2020 18:23:34

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:26', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'df8cfb3c-2aa8-4c57-b21a-4a13950c3961'	System	18 Aug 2020 18:23:34
User entered 'No (N)'	System	18 Aug 2020 18:23:34

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:30', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'df8cfb3c-2aa8-4c57-b21a-4a13950c3961'	System	18 Aug 2020 18:23:34
User entered '18 Aug 2020 14:23'	System	18 Aug 2020 18:23:34

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 6'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:39:23', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '99426670-ce5b-46ff-a0e7-d32611295906' User entered 'Yes (Y)'	System	19 Aug 2020 16:39:35
	System	19 Aug 2020 16:39:35

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:39:27', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '99426670-ce5b-46ff-a0e7-d32611295906' User entered '97.2'	System	19 Aug 2020 16:39:35
	System	19 Aug 2020 16:39:35

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:39:30', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '99426670-ce5b-46ff-a0e7-d32611295906'	System	19 Aug 2020 16:39:35
User entered 'No (N)'	System	19 Aug 2020 16:39:35

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:39:32', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '99426670-ce5b-46ff-a0e7-d32611295906'	System	19 Aug 2020 16:39:35
User entered '19 Aug 2020 12:39'	System	19 Aug 2020 16:39:35

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 7'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:26', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'b3fd65f8-6c44-4143-9a65-3830cdbf6313' User entered 'Yes (Y)'	System	20 Aug 2020 16:39:40
	System	20 Aug 2020 16:39:40

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:32', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'b3fd65f8-6c44-4143-9a65-3830cdbf6313' User entered '97.4'	System	20 Aug 2020 16:39:40
	System	20 Aug 2020 16:39:40

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:35', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'b3fd65f8-6c44-4143-9a65-3830cdbf6313'	System	20 Aug 2020 16:39:40
User entered 'No (N)'	System	20 Aug 2020 16:39:40

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:39', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'b3fd65f8-6c44-4143-9a65-3830cdbf6313' User entered '20 Aug 2020 12:39'	System	20 Aug 2020 16:39:40
	System	20 Aug 2020 16:39:40

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:43', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f9e8d7eb-dda6-4b23-bbae-eca09bb5382e' User entered 'None (1)'	System	14 Aug 2020 16:16:00
	System	14 Aug 2020 16:16:00

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:46', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f9e8d7eb-dda6-4b23-bbae-eca09bb5382e' User entered 'No (N)'	System	14 Aug 2020 16:16:00
	System	14 Aug 2020 16:16:00

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:49', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f9e8d7eb-dda6-4b23-bbae-eca09bb5382e' User entered 'No (N)'	System	14 Aug 2020 16:16:00
	System	14 Aug 2020 16:16:00

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:53', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f9e8d7eb-dda6-4b23-bbae-eca09bb5382e' User entered 'None (1)'	System	14 Aug 2020 16:16:00
	System	14 Aug 2020 16:16:00

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:15:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f9e8d7eb-dda6-4b23-bbae-eca09bb5382e' User entered '14 Aug 2020 12:15'	System	14 Aug 2020 16:16:00
	System	14 Aug 2020 16:16:00

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 12:05'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 14:35'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 15:30'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 2'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:32:56', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f050d8cd-9643-4c83-8745-c883209f058c'	System	15 Aug 2020 16:33:09
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 16:33:09

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:32:59', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f050d8cd-9643-4c83-8745-c883209f058c' User entered 'No (N)'	System	15 Aug 2020 16:33:09
	System	15 Aug 2020 16:33:09

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:01', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f050d8cd-9643-4c83-8745-c883209f058c' User entered 'No (N)'	System	15 Aug 2020 16:33:09
	System	15 Aug 2020 16:33:09

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f050d8cd-9643-4c83-8745-c883209f058c' User entered 'None (1)'	System	15 Aug 2020 16:33:09
	System	15 Aug 2020 16:33:09

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f050d8cd-9643-4c83-8745-c883209f058c' User entered '15 Aug 2020 12:33'	System	15 Aug 2020 16:33:09
	System	15 Aug 2020 16:33:09

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 3'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:08', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ba44467d-5cd9-4fd4-b801-af4bbeaa3ea6'	System	17 Aug 2020 00:53:20
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 00:53:20

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:10', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ba44467d-5cd9-4fd4-b801-af4bbeaa3ea6'	System	17 Aug 2020 00:53:20
User entered 'No (N)'	System	17 Aug 2020 00:53:20

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:12', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ba44467d-5cd9-4fd4-b801-af4bbeaa3ea6'	System	17 Aug 2020 00:53:20
User entered 'No (N)'	System	17 Aug 2020 00:53:20

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:14', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ba44467d-5cd9-4fd4-b801-af4bbeaa3ea6'	System	17 Aug 2020 00:53:20
User entered 'None (1)'	System	17 Aug 2020 00:53:20

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:16', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ba44467d-5cd9-4fd4-b801-af4bbeaa3ea6' User entered '16 Aug 2020 20:53'	System	17 Aug 2020 00:53:20
	System	17 Aug 2020 00:53:20

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 4'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:30:58', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c4c5ca0d-2487-4e77-beec-884eb7cbef70' User entered 'None (1)'	System	17 Aug 2020 19:31:11
	System	17 Aug 2020 19:31:11

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c4c5ca0d-2487-4e77-beec-884eb7cbef70' User entered 'No (N)'	System	17 Aug 2020 19:31:11
	System	17 Aug 2020 19:31:11

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:03', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c4c5ca0d-2487-4e77-beec-884eb7cbef70' User entered 'No (N)'	System	17 Aug 2020 19:31:11
	System	17 Aug 2020 19:31:11

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c4c5ca0d-2487-4e77-beec-884eb7cbef70' User entered 'None (1)'	System	17 Aug 2020 19:31:11
	System	17 Aug 2020 19:31:11

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c4c5ca0d-2487-4e77-beec-884eb7cbef70' User entered '17 Aug 2020 15:31'	System	17 Aug 2020 19:31:11
	System	17 Aug 2020 19:31:11

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 5'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:35', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f7cc02b6-6aa4-4729-8af4-bbf79c72e7c2'	System	18 Aug 2020 18:23:45
User entered 'None (1)'	System	18 Aug 2020 18:23:45

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:38', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f7cc02b6-6aa4-4729-8af4-bbf79c72e7c2'	System	18 Aug 2020 18:23:45
User entered 'No (N)'	System	18 Aug 2020 18:23:45

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:39', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f7cc02b6-6aa4-4729-8af4-bbf79c72e7c2'	System	18 Aug 2020 18:23:45
User entered 'No (N)'	System	18 Aug 2020 18:23:45

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:41', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f7cc02b6-6aa4-4729-8af4-bbf79c72e7c2' User entered 'None (1)'	System	18 Aug 2020 18:23:45
	System	18 Aug 2020 18:23:45

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:43', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f7cc02b6-6aa4-4729-8af4-bbf79c72e7c2' User entered '18 Aug 2020 14:23'	System	18 Aug 2020 18:23:45
	System	18 Aug 2020 18:23:45

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 6'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:39:36', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f4be8203-c12d-4f37-9348-3ee27716c7c3'	System	19 Aug 2020 16:40:57
User entered 'None (1)'	System	19 Aug 2020 16:40:57

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:39:38', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f4be8203-c12d-4f37-9348-3ee27716c7c3'	System	19 Aug 2020 16:40:57
User entered 'No (N)'	System	19 Aug 2020 16:40:57

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:40:46', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f4be8203-c12d-4f37-9348-3ee27716c7c3'	System	19 Aug 2020 16:40:57
User entered 'No (N)'	System	19 Aug 2020 16:40:57

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:40:53', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f4be8203-c12d-4f37-9348-3ee27716c7c3'	System	19 Aug 2020 16:40:57
User entered 'None (1)'	System	19 Aug 2020 16:40:57

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:40:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'f4be8203-c12d-4f37-9348-3ee27716c7c3'	System	19 Aug 2020 16:40:57
User entered '19 Aug 2020 12:40'	System	19 Aug 2020 16:40:57

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 7'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:42', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '48616393-22d1-4fac-906d-163c5b02b53d' User entered 'None (1)'	System	20 Aug 2020 16:39:59
	System	20 Aug 2020 16:39:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:45', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '48616393-22d1-4fac-906d-163c5b02b53d' User entered 'No (N)'	System	20 Aug 2020 16:39:59
	System	20 Aug 2020 16:39:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:47', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '48616393-22d1-4fac-906d-163c5b02b53d' User entered 'No (N)'	System	20 Aug 2020 16:39:59
	System	20 Aug 2020 16:39:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:48', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '48616393-22d1-4fac-906d-163c5b02b53d'	System	20 Aug 2020 16:39:59
User entered 'None (1)'	System	20 Aug 2020 16:39:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:39:57', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '48616393-22d1-4fac-906d-163c5b02b53d' User entered '20 Aug 2020 12:39'	System	20 Aug 2020 16:39:59
	System	20 Aug 2020 16:39:59

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:16:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '83d96251-40b8-4055-a09e-6e7510b46cac' User entered 'None (0)'	System	14 Aug 2020 16:16:16
	System	14 Aug 2020 16:16:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:16:02', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '83d96251-40b8-4055-a09e-6e7510b46cac' User entered 'None (0)'	System	14 Aug 2020 16:16:16
	System	14 Aug 2020 16:16:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:16:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '83d96251-40b8-4055-a09e-6e7510b46cac' User entered 'None (0)'	System	14 Aug 2020 16:16:16
	System	14 Aug 2020 16:16:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:16:05', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '83d96251-40b8-4055-a09e-6e7510b46cac' User entered 'None (0)'	System	14 Aug 2020 16:16:16
	System	14 Aug 2020 16:16:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:16:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '83d96251-40b8-4055-a09e-6e7510b46cac' User entered 'None (0)'	System	14 Aug 2020 16:16:16
	System	14 Aug 2020 16:16:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:16:08', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '83d96251-40b8-4055-a09e-6e7510b46cac' User entered 'None (0)'	System	14 Aug 2020 16:16:16
	System	14 Aug 2020 16:16:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:16:11', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '83d96251-40b8-4055-a09e-6e7510b46cac'	System	14 Aug 2020 16:16:16
User entered 'No (N)'	System	14 Aug 2020 16:16:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-14T12:16:14', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '83d96251-40b8-4055-a09e-6e7510b46cac'	System	14 Aug 2020 16:16:16
User entered '14 Aug 2020 12:16'	System	14 Aug 2020 16:16:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 12:05'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 14:35'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '14 Aug 2020 15:30'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 2'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:15', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a58f258e-e6eb-4606-92f3-1ff7db96c07c' User entered 'None (0)'	System	15 Aug 2020 16:33:36
	System	15 Aug 2020 16:33:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:19', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a58f258e-e6eb-4606-92f3-1ff7db96c07c' User entered 'None (0)'	System	15 Aug 2020 16:33:36
	System	15 Aug 2020 16:33:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:21', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a58f258e-e6eb-4606-92f3-1ff7db96c07c' User entered 'None (0)'	System	15 Aug 2020 16:33:36
	System	15 Aug 2020 16:33:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:23', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a58f258e-e6eb-4606-92f3-1ff7db96c07c' User entered 'None (0)'	System	15 Aug 2020 16:33:36
	System	15 Aug 2020 16:33:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:25', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a58f258e-e6eb-4606-92f3-1ff7db96c07c' User entered 'None (0)'	System	15 Aug 2020 16:33:36
	System	15 Aug 2020 16:33:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:27', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a58f258e-e6eb-4606-92f3-1ff7db96c07c' User entered 'None (0)'	System	15 Aug 2020 16:33:36
	System	15 Aug 2020 16:33:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:30', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a58f258e-e6eb-4606-92f3-1ff7db96c07c' User entered 'No (N)'	System	15 Aug 2020 16:33:36
	System	15 Aug 2020 16:33:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-15T12:33:32', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a58f258e-e6eb-4606-92f3-1ff7db96c07c' User entered '15 Aug 2020 12:33'	System	15 Aug 2020 16:33:36
	System	15 Aug 2020 16:33:36

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 3'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:20', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '766c27ff-5926-4346-af7b-f4efb1402a98'	System	17 Aug 2020 00:53:35
User entered 'None (0)'	System	17 Aug 2020 00:53:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:21', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '766c27ff-5926-4346-af7b-f4efb1402a98' User entered 'None (0)'	System	17 Aug 2020 00:53:35
	System	17 Aug 2020 00:53:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:23', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '766c27ff-5926-4346-af7b-f4efb1402a98'	System	17 Aug 2020 00:53:35
User entered 'None (0)'	System	17 Aug 2020 00:53:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:24', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '766c27ff-5926-4346-af7b-f4efb1402a98' User entered 'None (0)'	System	17 Aug 2020 00:53:35
	System	17 Aug 2020 00:53:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:26', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '766c27ff-5926-4346-af7b-f4efb1402a98'	System	17 Aug 2020 00:53:35
User entered 'None (0)'	System	17 Aug 2020 00:53:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:27', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '766c27ff-5926-4346-af7b-f4efb1402a98'	System	17 Aug 2020 00:53:35
User entered 'None (0)'	System	17 Aug 2020 00:53:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:30', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '766c27ff-5926-4346-af7b-f4efb1402a98'	System	17 Aug 2020 00:53:35
User entered 'No (N)'	System	17 Aug 2020 00:53:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-16T20:53:32', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '766c27ff-5926-4346-af7b-f4efb1402a98'	System	17 Aug 2020 00:53:35
User entered '16 Aug 2020 20:53'	System	17 Aug 2020 00:53:35

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 4'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:10', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7e87ef5d-65ec-4252-a6cc-046369246c1d' User entered 'None (0)'	System	17 Aug 2020 19:31:23
	System	17 Aug 2020 19:31:23

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:12', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7e87ef5d-65ec-4252-a6cc-046369246c1d' User entered 'None (0)'	System	17 Aug 2020 19:31:23
	System	17 Aug 2020 19:31:23

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:13', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7e87ef5d-65ec-4252-a6cc-046369246c1d' User entered 'None (0)'	System	17 Aug 2020 19:31:23
	System	17 Aug 2020 19:31:23

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:14', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7e87ef5d-65ec-4252-a6cc-046369246c1d' User entered 'None (0)'	System	17 Aug 2020 19:31:23
	System	17 Aug 2020 19:31:23

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:15', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7e87ef5d-65ec-4252-a6cc-046369246c1d' User entered 'None (0)'	System	17 Aug 2020 19:31:23
	System	17 Aug 2020 19:31:23

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:17', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7e87ef5d-65ec-4252-a6cc-046369246c1d' User entered 'None (0)'	System	17 Aug 2020 19:31:23
	System	17 Aug 2020 19:31:23

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:19', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7e87ef5d-65ec-4252-a6cc-046369246c1d' User entered 'No (N)'	System	17 Aug 2020 19:31:23
	System	17 Aug 2020 19:31:23

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-17T15:31:21', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7e87ef5d-65ec-4252-a6cc-046369246c1d' User entered '17 Aug 2020 15:31'	System	17 Aug 2020 19:31:23
	System	17 Aug 2020 19:31:23

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 5'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:49', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '37176811-f509-48e8-868a-59af04330b1c'	System	18 Aug 2020 18:24:08
User entered 'No interference with activity (1)'	System	18 Aug 2020 18:24:08

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:51', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '37176811-f509-48e8-868a-59af04330b1c' User entered 'None (0)'	System	18 Aug 2020 18:24:08
	System	18 Aug 2020 18:24:08

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '37176811-f509-48e8-868a-59af04330b1c' User entered 'None (0)'	System	18 Aug 2020 18:24:08
	System	18 Aug 2020 18:24:08

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:56', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '37176811-f509-48e8-868a-59af04330b1c' User entered 'None (0)'	System	18 Aug 2020 18:24:08
	System	18 Aug 2020 18:24:08

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:23:59', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '37176811-f509-48e8-868a-59af04330b1c' User entered 'None (0)'	System	18 Aug 2020 18:24:08
	System	18 Aug 2020 18:24:08

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:24:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '37176811-f509-48e8-868a-59af04330b1c' User entered 'None (0)'	System	18 Aug 2020 18:24:08
	System	18 Aug 2020 18:24:08

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:24:02', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '37176811-f509-48e8-868a-59af04330b1c' User entered 'No (N)'	System	18 Aug 2020 18:24:08
	System	18 Aug 2020 18:24:08

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-18T14:24:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '37176811-f509-48e8-868a-59af04330b1c' User entered '18 Aug 2020 14:24'	System	18 Aug 2020 18:24:08
	System	18 Aug 2020 18:24:08

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 6'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:41:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b88fd0a-fc09-46cf-9795-30660e498270' User entered 'None (0)'	System	19 Aug 2020 16:41:17
	System	19 Aug 2020 16:41:17

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:41:02', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b88fd0a-fc09-46cf-9795-30660e498270' User entered 'None (0)'	System	19 Aug 2020 16:41:17
	System	19 Aug 2020 16:41:17

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:41:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b88fd0a-fc09-46cf-9795-30660e498270' User entered 'None (0)'	System	19 Aug 2020 16:41:17
	System	19 Aug 2020 16:41:17

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:41:05', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b88fd0a-fc09-46cf-9795-30660e498270' User entered 'None (0)'	System	19 Aug 2020 16:41:17
	System	19 Aug 2020 16:41:17

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:41:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b88fd0a-fc09-46cf-9795-30660e498270' User entered 'None (0)'	System	19 Aug 2020 16:41:17
	System	19 Aug 2020 16:41:17

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:41:08', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b88fd0a-fc09-46cf-9795-30660e498270' User entered 'None (0)'	System	19 Aug 2020 16:41:17
	System	19 Aug 2020 16:41:17

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:41:10', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b88fd0a-fc09-46cf-9795-30660e498270' User entered 'No (N)'	System	19 Aug 2020 16:41:17
	System	19 Aug 2020 16:41:17

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-19T12:41:12', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b88fd0a-fc09-46cf-9795-30660e498270' User entered '19 Aug 2020 12:41'	System	19 Aug 2020 16:41:17
	System	19 Aug 2020 16:41:17

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 7'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:40:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '78b995be-9c3a-4c02-9220-2569ec95e09e' User entered 'None (0)'	System	20 Aug 2020 16:40:16
	System	20 Aug 2020 16:40:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:40:02', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '78b995be-9c3a-4c02-9220-2569ec95e09e' User entered 'None (0)'	System	20 Aug 2020 16:40:16
	System	20 Aug 2020 16:40:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:40:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '78b995be-9c3a-4c02-9220-2569ec95e09e' User entered 'None (0)'	System	20 Aug 2020 16:40:16
	System	20 Aug 2020 16:40:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:40:06', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '78b995be-9c3a-4c02-9220-2569ec95e09e' User entered 'None (0)'	System	20 Aug 2020 16:40:16
	System	20 Aug 2020 16:40:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:40:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '78b995be-9c3a-4c02-9220-2569ec95e09e' User entered 'None (0)'	System	20 Aug 2020 16:40:16
	System	20 Aug 2020 16:40:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:40:09', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '78b995be-9c3a-4c02-9220-2569ec95e09e' User entered 'None (0)'	System	20 Aug 2020 16:40:16
	System	20 Aug 2020 16:40:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:40:11', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '78b995be-9c3a-4c02-9220-2569ec95e09e' User entered 'No (N)'	System	20 Aug 2020 16:40:16
	System	20 Aug 2020 16:40:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-08-20T12:40:14', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '78b995be-9c3a-4c02-9220-2569ec95e09e' User entered '20 Aug 2020 12:40'	System	20 Aug 2020 16:40:16
	System	20 Aug 2020 16:40:16

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:56:13

US3222143

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:55:46

US3222143

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '21 Aug 2020'	Jennifer Dittman (b) (4)	16 Sep 2020 17:55:46

US3222143

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:55:46

US3222143

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	Jennifer Dittman (b) (4)	16 Sep 2020 17:55:46

US3222143

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:55:50

US3222143

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	16 Sep 2020 17:55:50

US3222143

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:13

US3222143

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '28 Aug 2020'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:13

US3222143

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:13

US3222143

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:13

US3222143

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:17

US3222143

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	16 Sep 2020 17:56:17

US3222143

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:39

US3222143

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '06 Sep 2020'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:39

US3222143

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:39

US3222143

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:39

US3222143

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:43

US3222143

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	16 Sep 2020 17:56:43

US3222143

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:54

US3222143

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16 Sep 2020'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:54

US3222143

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:56:54

US3222143

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'VISIT2'	System	16 Sep 2020 17:56:54

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16 Sep 2020'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '12:45'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '16 Sep 2020 12:45'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '36.4' C	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '56'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'bpm'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'breaths/min'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '118'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'mmHg'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '70'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'mmHg'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16 Sep 2020'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '14:11'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '16 Sep 2020 14:11'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '36.5' C	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '60'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'bpm'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'breaths/min'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '116'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'mmHg'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '70'	Albert Garcia (b) (4)	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'mmHg'	System	16 Sep 2020 18:59:35

US3222143

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 18:59:55

US3222143

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16 Sep 2020'	Albert Garcia (b) (4)	16 Sep 2020 18:59:55

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Albert Garcia (b) (4)	16 Sep 2020 19:00:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16 Sep 2020'	Albert Garcia (b) (4)	16 Sep 2020 19:00:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Urine (URINE)'	Albert Garcia (b) (4)	16 Sep 2020 19:00:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Negative (NEGATIVE)'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:00:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	16 Sep 2020 19:00:27
User entered empty.	(b) (4)	
	Albert Garcia (b) (4)	16 Sep 2020 19:00:17
	(b) (4)	

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Albert Garcia (b) (4)	16 Sep 2020 19:00:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Albert Garcia (b) (4)	16 Sep 2020 19:00:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	16 Sep 2020 19:00:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Jennifer Dittman (b) (4)	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

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)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Jennifer Dittman (b) (4)	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16 Sep 2020'	Jennifer Dittman (b) (4)	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '13:40'	Jennifer Dittman (b) (4)	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '16 Sep 2020 13:40'	System	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'ONCE'	System	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 17:57:17

US3222143

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Albert Garcia (b) (4)	16 Sep 2020 19:00:51

US3222143

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16 Sep 2020'	Albert Garcia (b) (4)	16 Sep 2020 19:00:51

US3222143

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '13:26'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:00:51

US3222143

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '16 Sep 2020 13:26'	System	16 Sep 2020 19:00:51

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:03:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '16 Sep 2020'	Albert Garcia (b) (4)	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Albert Garcia (b) (4)	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '13:30'	Albert Garcia (b) (4)	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '16 Sep 2020 13:30'	System	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	Albert Garcia (b) (4)	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Albert Garcia (b) (4)	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	16 Sep 2020 19:01:04

US3222143

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	16 Sep 2020 17:57:28

US3222143

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '1'	System	16 Sep 2020 17:57:28

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:05:58', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b5e895e-ed7e-440e-abaa-ef5f0a73c759' User entered 'Yes (Y)'	System	16 Sep 2020 18:06:10
	System	16 Sep 2020 18:06:10

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:02', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b5e895e-ed7e-440e-abaa-ef5f0a73c759' User entered '97.7'	System	16 Sep 2020 18:06:10
	System	16 Sep 2020 18:06:10

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b5e895e-ed7e-440e-abaa-ef5f0a73c759'	System	16 Sep 2020 18:06:10
User entered 'No (N)'	System	16 Sep 2020 18:06:10

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b5e895e-ed7e-440e-abaa-ef5f0a73c759' User entered '16 Sep 2020 14:06'	System	16 Sep 2020 18:06:10
	System	16 Sep 2020 18:06:10

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 14:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 16:30'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 17:25'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 2'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:33:09', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '88a8580e-e45a-49b2-9199-d5c685c78cec' User entered 'Yes (Y)'	System	17 Sep 2020 17:43:14
	System	17 Sep 2020 17:43:14

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:33:13', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '88a8580e-e45a-49b2-9199-d5c685c78cec' User entered '98.4'	System	17 Sep 2020 17:43:14
	System	17 Sep 2020 17:43:14

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Comment added 'pt took Tylenol 650mg every 6 hours for 24 hours for headache'.	(b) (4), (b) (6)	07 Oct 2020 14:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:33:17', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '88a8580e-e45a-49b2-9199-d5c685c78cec'	System	17 Sep 2020 17:43:14
User entered 'Yes (Y)'	System	17 Sep 2020 17:43:14

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Grade 2. Took 220 mg Aleve for site injection pain.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 07:38:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '88a8580e-e45a-49b2-9199-d5c685c78cec' User entered '1'	douglas winter (b) (4) (b) (4)	07 Oct 2020 11:12:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Sep 2020 17:43:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '88a8580e-e45a-49b2-9199-d5c685c78cec' User entered '1'	System	17 Sep 2020 17:43:14
User entered '1'	System	17 Sep 2020 17:43:14

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '88a8580e-e45a-49b2-9199-d5c685c78cec' User entered '0'	System	17 Sep 2020 17:43:14
	System	17 Sep 2020 17:43:14

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:12', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '88a8580e-e45a-49b2-9199-d5c685c78cec' User entered '17 Sep 2020 13:43'	System	17 Sep 2020 17:43:14
	System	17 Sep 2020 17:43:14

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 3'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:22', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'fd4d3be1-5f32-4343-b2c9-58b111f15a76' User entered 'Yes (Y)'	System	18 Sep 2020 20:50:37
	System	18 Sep 2020 20:50:37

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:25', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'fd4d3be1-5f32-4343-b2c9-58b111f15a76' User entered '97.4'	System	18 Sep 2020 20:50:37
	System	18 Sep 2020 20:50:37

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:28', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'fd4d3be1-5f32-4343-b2c9-58b111f15a76'	System	18 Sep 2020 20:50:37
User entered 'Yes (Y)'	System	18 Sep 2020 20:50:37

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Grade 2. Took 220 mg Aleve for site injection pain.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 07:38:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:31', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'fd4d3be1-5f32-4343-b2c9-58b111f15a76' User entered '1'	douglas winter (b) (4) (b) (4)	07 Oct 2020 11:13:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	18 Sep 2020 20:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:31', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'fd4d3be1-5f32-4343-b2c9-58b111f15a76' User entered '1'	System	18 Sep 2020 20:50:37
User entered '1'	System	18 Sep 2020 20:50:37

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:31', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'fd4d3be1-5f32-4343-b2c9-58b111f15a76' User entered '0'	System	18 Sep 2020 20:50:37
	System	18 Sep 2020 20:50:37

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:33', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'fd4d3be1-5f32-4343-b2c9-58b111f15a76'	System	18 Sep 2020 20:50:37
User entered '18 Sep 2020 16:50'	System	18 Sep 2020 20:50:37

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 4'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:35', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2b56c19b-5d68-4f10-ab6a-428c41e26a03'	System	19 Sep 2020 21:26:49
User entered 'Yes (Y)'	System	19 Sep 2020 21:26:49

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:39', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2b56c19b-5d68-4f10-ab6a-428c41e26a03' User entered '96.4'	System	19 Sep 2020 21:26:49
	System	19 Sep 2020 21:26:49

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:44', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2b56c19b-5d68-4f10-ab6a-428c41e26a03'	System	19 Sep 2020 21:26:49
User entered 'No (N)'	System	19 Sep 2020 21:26:49

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:46', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2b56c19b-5d68-4f10-ab6a-428c41e26a03'	System	19 Sep 2020 21:26:49
User entered '19 Sep 2020 17:26'	System	19 Sep 2020 21:26:49

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 5'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:14', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '76f07d61-de54-4c68-a89e-f05c31ccd161' User entered 'Yes (Y)'	System	20 Sep 2020 18:19:28
	System	20 Sep 2020 18:19:28

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:18', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '76f07d61-de54-4c68-a89e-f05c31ccd161' User entered '97.5'	System	20 Sep 2020 18:19:28
	System	20 Sep 2020 18:19:28

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:24', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '76f07d61-de54-4c68-a89e-f05c31ccd161' User entered 'No (N)'	System	20 Sep 2020 18:19:28
	System	20 Sep 2020 18:19:28

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:26', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '76f07d61-de54-4c68-a89e-f05c31ccd161' User entered '20 Sep 2020 14:19'	System	20 Sep 2020 18:19:28
	System	20 Sep 2020 18:19:28

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 6'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:00:35', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '4b8897fc-0513-464f-9798-bb3b225cd953'	System	22 Sep 2020 01:00:49
User entered 'Yes (Y)'	System	22 Sep 2020 01:00:49

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:00:42', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '4b8897fc-0513-464f-9798-bb3b225cd953' User entered '97.5'	System	22 Sep 2020 01:00:49
	System	22 Sep 2020 01:00:49

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:00:44', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '4b8897fc-0513-464f-9798-bb3b225cd953'	System	22 Sep 2020 01:00:49
User entered 'No (N)'	System	22 Sep 2020 01:00:49

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:00:47', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '4b8897fc-0513-464f-9798-bb3b225cd953'	System	22 Sep 2020 01:00:49
User entered '21 Sep 2020 21:00'	System	22 Sep 2020 01:00:49

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 7'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:12', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '12d588d0-0dff-422c-9256-7dae17d24069' User entered 'Yes (Y)'	System	23 Sep 2020 01:33:23
	System	23 Sep 2020 01:33:23

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:17', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '12d588d0-0dff-422c-9256-7dae17d24069' User entered '97.2'	System	23 Sep 2020 01:33:23
	System	23 Sep 2020 01:33:23

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:20', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '12d588d0-0dff-422c-9256-7dae17d24069'	System	23 Sep 2020 01:33:23
User entered 'No (N)'	System	23 Sep 2020 01:33:23

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:22', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '12d588d0-0dff-422c-9256-7dae17d24069' User entered '22 Sep 2020 21:33'	System	23 Sep 2020 01:33:23
	System	23 Sep 2020 01:33:23

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:05:29', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c522a1e9-240b-4fb1-9b4b-a6c06bec32f0' User entered 'None (1)'	System	16 Sep 2020 18:05:56
	System	16 Sep 2020 18:05:56

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:05:44', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c522a1e9-240b-4fb1-9b4b-a6c06bec32f0' User entered 'No (N)'	System	16 Sep 2020 18:05:56
	System	16 Sep 2020 18:05:56

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:05:46', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c522a1e9-240b-4fb1-9b4b-a6c06bec32f0' User entered 'No (N)'	System	16 Sep 2020 18:05:56
	System	16 Sep 2020 18:05:56

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:05:50', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c522a1e9-240b-4fb1-9b4b-a6c06bec32f0' User entered 'None (1)'	System	16 Sep 2020 18:05:56
	System	16 Sep 2020 18:05:56

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:05:54', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'c522a1e9-240b-4fb1-9b4b-a6c06bec32f0' User entered '16 Sep 2020 14:05'	System	16 Sep 2020 18:05:56
	System	16 Sep 2020 18:05:56

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 14:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 16:30'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 17:25'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 2'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:21', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '31f10195-72b3-4ce5-a0db-1d9385565633'	System	17 Sep 2020 17:43:46
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Sep 2020 17:43:46

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:28', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '31f10195-72b3-4ce5-a0db-1d9385565633'	System	17 Sep 2020 17:43:46
User entered 'No (N)'	System	17 Sep 2020 17:43:46

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:34', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '31f10195-72b3-4ce5-a0db-1d9385565633'	System	17 Sep 2020 17:43:46
User entered 'No (N)'	System	17 Sep 2020 17:43:46

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:39', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '31f10195-72b3-4ce5-a0db-1d9385565633'	System	17 Sep 2020 17:43:46
User entered 'None (1)'	System	17 Sep 2020 17:43:46

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:42', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '31f10195-72b3-4ce5-a0db-1d9385565633'	System	17 Sep 2020 17:43:46
User entered '17 Sep 2020 13:43'	System	17 Sep 2020 17:43:46

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 3'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:40', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '55cab856-6239-48f1-8510-b96c6c32a691'	System	18 Sep 2020 20:51:01
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 20:51:01

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:42', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '55cab856-6239-48f1-8510-b96c6c32a691' User entered 'No (N)'	System	18 Sep 2020 20:51:01
	System	18 Sep 2020 20:51:01

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '55cab856-6239-48f1-8510-b96c6c32a691' User entered 'No (N)'	System	18 Sep 2020 20:51:01
	System	18 Sep 2020 20:51:01

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:50:57', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '55cab856-6239-48f1-8510-b96c6c32a691' User entered 'None (1)'	System	18 Sep 2020 20:51:01
	System	18 Sep 2020 20:51:01

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '55cab856-6239-48f1-8510-b96c6c32a691' User entered '18 Sep 2020 16:51'	System	18 Sep 2020 20:51:01
	System	18 Sep 2020 20:51:01

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 4'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:17', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '05e3f72c-2579-4aeb-8c2a-d0f61a003f70' User entered 'None (1)'	System	19 Sep 2020 21:26:27
	System	19 Sep 2020 21:26:27

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:19', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '05e3f72c-2579-4aeb-8c2a-d0f61a003f70' User entered 'No (N)'	System	19 Sep 2020 21:26:27
	System	19 Sep 2020 21:26:27

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:21', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '05e3f72c-2579-4aeb-8c2a-d0f61a003f70' User entered 'No (N)'	System	19 Sep 2020 21:26:27
	System	19 Sep 2020 21:26:27

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:23', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '05e3f72c-2579-4aeb-8c2a-d0f61a003f70'	System	19 Sep 2020 21:26:27
User entered 'None (1)'	System	19 Sep 2020 21:26:27

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:26', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '05e3f72c-2579-4aeb-8c2a-d0f61a003f70' User entered '19 Sep 2020 17:26'	System	19 Sep 2020 21:26:27
	System	19 Sep 2020 21:26:27

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 5'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:29', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b85d678-3cad-411e-85da-c57ee5c43004'	System	20 Sep 2020 18:19:40
User entered 'None (1)'	System	20 Sep 2020 18:19:40

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:31', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b85d678-3cad-411e-85da-c57ee5c43004'	System	20 Sep 2020 18:19:40
User entered 'No (N)'	System	20 Sep 2020 18:19:40

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:33', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b85d678-3cad-411e-85da-c57ee5c43004'	System	20 Sep 2020 18:19:40
User entered 'No (N)'	System	20 Sep 2020 18:19:40

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:35', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b85d678-3cad-411e-85da-c57ee5c43004'	System	20 Sep 2020 18:19:40
User entered 'None (1)'	System	20 Sep 2020 18:19:40

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:37', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b85d678-3cad-411e-85da-c57ee5c43004' User entered '20 Sep 2020 14:19'	System	20 Sep 2020 18:19:40
	System	20 Sep 2020 18:19:40

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 6'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:00:49', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e1019d0e-7a91-4340-be70-e3e3db0f8f45' User entered 'None (1)'	System	22 Sep 2020 01:01:15
	System	22 Sep 2020 01:01:15

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:00:51', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e1019d0e-7a91-4340-be70-e3e3db0f8f45'	System	22 Sep 2020 01:01:15
User entered 'No (N)'	System	22 Sep 2020 01:01:15

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:00:56', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e1019d0e-7a91-4340-be70-e3e3db0f8f45'	System	22 Sep 2020 01:01:15
User entered 'No (N)'	System	22 Sep 2020 01:01:15

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:00:59', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e1019d0e-7a91-4340-be70-e3e3db0f8f45' User entered 'None (1)'	System	22 Sep 2020 01:01:15
	System	22 Sep 2020 01:01:15

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:01', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e1019d0e-7a91-4340-be70-e3e3db0f8f45'	System	22 Sep 2020 01:01:15
User entered '21 Sep 2020 21:01'	System	22 Sep 2020 01:01:15

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 7'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:25', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7b7a3fb8-1aee-424a-b610-5cb51c5a72b3' User entered 'None (1)'	System	23 Sep 2020 01:33:38
	System	23 Sep 2020 01:33:38

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:29', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7b7a3fb8-1aee-424a-b610-5cb51c5a72b3' User entered 'No (N)'	System	23 Sep 2020 01:33:38
	System	23 Sep 2020 01:33:38

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:31', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7b7a3fb8-1aee-424a-b610-5cb51c5a72b3' User entered 'No (N)'	System	23 Sep 2020 01:33:38
	System	23 Sep 2020 01:33:38

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:33', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7b7a3fb8-1aee-424a-b610-5cb51c5a72b3' User entered 'None (1)'	System	23 Sep 2020 01:33:38
	System	23 Sep 2020 01:33:38

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:36', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7b7a3fb8-1aee-424a-b610-5cb51c5a72b3' User entered '22 Sep 2020 21:33'	System	23 Sep 2020 01:33:38
	System	23 Sep 2020 01:33:38

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:10', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '8578a042-6445-4adf-a7e4-bca437a12fba' User entered 'None (0)'	System	16 Sep 2020 18:06:24
	System	16 Sep 2020 18:06:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:11', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '8578a042-6445-4adf-a7e4-bca437a12fba' User entered 'None (0)'	System	16 Sep 2020 18:06:24
	System	16 Sep 2020 18:06:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:12', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '8578a042-6445-4adf-a7e4-bca437a12fba' User entered 'None (0)'	System	16 Sep 2020 18:06:24
	System	16 Sep 2020 18:06:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:14', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '8578a042-6445-4adf-a7e4-bca437a12fba' User entered 'None (0)'	System	16 Sep 2020 18:06:24
	System	16 Sep 2020 18:06:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:15', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '8578a042-6445-4adf-a7e4-bca437a12fba' User entered 'None (0)'	System	16 Sep 2020 18:06:24
	System	16 Sep 2020 18:06:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:16', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '8578a042-6445-4adf-a7e4-bca437a12fba' User entered 'None (0)'	System	16 Sep 2020 18:06:24
	System	16 Sep 2020 18:06:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:17', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '8578a042-6445-4adf-a7e4-bca437a12fba' User entered 'No (N)'	System	16 Sep 2020 18:06:24
	System	16 Sep 2020 18:06:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-16T14:06:21', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '8578a042-6445-4adf-a7e4-bca437a12fba' User entered '16 Sep 2020 14:06'	System	16 Sep 2020 18:06:24
	System	16 Sep 2020 18:06:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 14:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 16:30'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '16 Sep 2020 17:25'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 2'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:51', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ca82d6ad-5c77-4f85-b594-2e03d8e485d0'	System	17 Sep 2020 17:44:39
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:44:39

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:43:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ca82d6ad-5c77-4f85-b594-2e03d8e485d0'	System	17 Sep 2020 17:44:39
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:44:39

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Comment added 'symptoms resolved in 24 hours'.	(b) (4), (b) (6)	07 Oct 2020 14:40:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:44:05', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ca82d6ad-5c77-4f85-b594-2e03d8e485d0'	System	17 Sep 2020 17:44:39
User entered 'Some interference with activity (2)'	System	17 Sep 2020 17:44:39

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:44:10', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ca82d6ad-5c77-4f85-b594-2e03d8e485d0' User entered 'None (0)'	System	17 Sep 2020 17:44:39
	System	17 Sep 2020 17:44:39

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:44:25', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ca82d6ad-5c77-4f85-b594-2e03d8e485d0'	System	17 Sep 2020 17:44:39
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Sep 2020 17:44:39

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:44:28', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ca82d6ad-5c77-4f85-b594-2e03d8e485d0'	System	17 Sep 2020 17:44:39
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:44:39

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:44:32', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ca82d6ad-5c77-4f85-b594-2e03d8e485d0' User entered 'No (N)'	System	17 Sep 2020 17:44:39
	System	17 Sep 2020 17:44:39

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-17T13:44:35', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ca82d6ad-5c77-4f85-b594-2e03d8e485d0' User entered '17 Sep 2020 13:44'	System	17 Sep 2020 17:44:39
	System	17 Sep 2020 17:44:39

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 3'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2cdbb09e-3fca-47eb-825d-4d88fbc769d3' User entered 'None (0)'	System	18 Sep 2020 20:51:27
	System	18 Sep 2020 20:51:27

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2cdbb09e-3fca-47eb-825d-4d88fbc769d3'	System	18 Sep 2020 20:51:27
User entered 'No interference with activity (1)'	System	18 Sep 2020 20:51:27

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:11', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2cdbb09e-3fca-47eb-825d-4d88fbc769d3'	System	18 Sep 2020 20:51:27
User entered 'No interference with activity (1)'	System	18 Sep 2020 20:51:27

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:13', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2cdbb09e-3fca-47eb-825d-4d88fbc769d3' User entered 'None (0)'	System	18 Sep 2020 20:51:27
	System	18 Sep 2020 20:51:27

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:14', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2cdbb09e-3fca-47eb-825d-4d88fbc769d3' User entered 'None (0)'	System	18 Sep 2020 20:51:27
	System	18 Sep 2020 20:51:27

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:16', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2cdbb09e-3fca-47eb-825d-4d88fbc769d3' User entered 'None (0)'	System	18 Sep 2020 20:51:27
	System	18 Sep 2020 20:51:27

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:19', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2cdbb09e-3fca-47eb-825d-4d88fbc769d3' User entered 'No (N)'	System	18 Sep 2020 20:51:27
	System	18 Sep 2020 20:51:27

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-18T16:51:23', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2cdbb09e-3fca-47eb-825d-4d88fbc769d3' User entered '18 Sep 2020 16:51'	System	18 Sep 2020 20:51:27
	System	18 Sep 2020 20:51:27

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 4'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Comment added 'took Tylenol 650 every 6 hours for 24 hours'.	(b) (4), (b) (6)	07 Oct 2020 14:07:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:51', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef84d25c-a26e-4ee5-b8c4-cc94cd41cb96'	System	19 Sep 2020 21:27:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Sep 2020 21:27:04

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:53', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef84d25c-a26e-4ee5-b8c4-cc94cd41cb96'	System	19 Sep 2020 21:27:04
User entered 'None (0)'	System	19 Sep 2020 21:27:04

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:54', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef84d25c-a26e-4ee5-b8c4-cc94cd41cb96' User entered 'None (0)'	System	19 Sep 2020 21:27:04
	System	19 Sep 2020 21:27:04

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef84d25c-a26e-4ee5-b8c4-cc94cd41cb96' User entered 'None (0)'	System	19 Sep 2020 21:27:04
	System	19 Sep 2020 21:27:04

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:56', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef84d25c-a26e-4ee5-b8c4-cc94cd41cb96' User entered 'None (0)'	System	19 Sep 2020 21:27:04
	System	19 Sep 2020 21:27:04

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:58', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef84d25c-a26e-4ee5-b8c4-cc94cd41cb96' User entered 'None (0)'	System	19 Sep 2020 21:27:04
	System	19 Sep 2020 21:27:04

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:26:59', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef84d25c-a26e-4ee5-b8c4-cc94cd41cb96'	System	19 Sep 2020 21:27:04
User entered 'No (N)'	System	19 Sep 2020 21:27:04

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-19T17:27:01', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef84d25c-a26e-4ee5-b8c4-cc94cd41cb96'	System	19 Sep 2020 21:27:04
User entered '19 Sep 2020 17:27'	System	19 Sep 2020 21:27:04

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 5'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Comment added 'pt states she took Tylenol 650 for 24 hours'.	(b) (4), (b) (6)	07 Oct 2020 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:48', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9eff9b60-4357-4c17-a9bf-9b212255d652'	System	20 Sep 2020 18:20:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	20 Sep 2020 18:20:08

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:52', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9eff9b60-4357-4c17-a9bf-9b212255d652'	System	20 Sep 2020 18:20:08
User entered 'No interference with activity (1)'	System	20 Sep 2020 18:20:08

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:54', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9eff9b60-4357-4c17-a9bf-9b212255d652' User entered 'None (0)'	System	20 Sep 2020 18:20:08
	System	20 Sep 2020 18:20:08

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9eff9b60-4357-4c17-a9bf-9b212255d652' User entered 'None (0)'	System	20 Sep 2020 18:20:08
	System	20 Sep 2020 18:20:08

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:57', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9eff9b60-4357-4c17-a9bf-9b212255d652' User entered 'None (0)'	System	20 Sep 2020 18:20:08
	System	20 Sep 2020 18:20:08

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:19:58', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9eff9b60-4357-4c17-a9bf-9b212255d652' User entered 'None (0)'	System	20 Sep 2020 18:20:08
	System	20 Sep 2020 18:20:08

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
Comment added 'Did not receive medical attention, yes was in error.'	douglas winter (b) (4)	07 Oct 2020 11:14:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:20:01', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9eff9b60-4357-4c17-a9bf-9b212255d652'	(b) (4)	
User entered 'Yes (Y)'	System	20 Sep 2020 18:20:08

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-20T14:20:03', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9eff9b60-4357-4c17-a9bf-9b212255d652'	System	20 Sep 2020 18:20:08
User entered '20 Sep 2020 14:20'	System	20 Sep 2020 18:20:08

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 6'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:06', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3fb16cc3-3223-47e1-977e-db9fa8c79c51' User entered 'None (0)'	System	22 Sep 2020 01:01:24
	System	22 Sep 2020 01:01:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3fb16cc3-3223-47e1-977e-db9fa8c79c51' User entered 'None (0)'	System	22 Sep 2020 01:01:24
	System	22 Sep 2020 01:01:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:08', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3fb16cc3-3223-47e1-977e-db9fa8c79c51' User entered 'None (0)'	System	22 Sep 2020 01:01:24
	System	22 Sep 2020 01:01:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:10', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3fb16cc3-3223-47e1-977e-db9fa8c79c51' User entered 'None (0)'	System	22 Sep 2020 01:01:24
	System	22 Sep 2020 01:01:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:11', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3fb16cc3-3223-47e1-977e-db9fa8c79c51' User entered 'None (0)'	System	22 Sep 2020 01:01:24
	System	22 Sep 2020 01:01:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:12', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3fb16cc3-3223-47e1-977e-db9fa8c79c51' User entered 'None (0)'	System	22 Sep 2020 01:01:24
	System	22 Sep 2020 01:01:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:14', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3fb16cc3-3223-47e1-977e-db9fa8c79c51' User entered 'No (N)'	System	22 Sep 2020 01:01:24
	System	22 Sep 2020 01:01:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-21T21:01:15', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3fb16cc3-3223-47e1-977e-db9fa8c79c51' User entered '21 Sep 2020 21:01'	System	22 Sep 2020 01:01:24
	System	22 Sep 2020 01:01:24

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	16 Sep 2020 17:57:17
User entered 'Day 7'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:42', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6b14a6cb-6c96-49a1-817f-a69cda7de955' User entered 'None (0)'	System	23 Sep 2020 01:33:56
	System	23 Sep 2020 01:33:56

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:44', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6b14a6cb-6c96-49a1-817f-a69cda7de955' User entered 'None (0)'	System	23 Sep 2020 01:33:56
	System	23 Sep 2020 01:33:56

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:45', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6b14a6cb-6c96-49a1-817f-a69cda7de955' User entered 'None (0)'	System	23 Sep 2020 01:33:56
	System	23 Sep 2020 01:33:56

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:47', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6b14a6cb-6c96-49a1-817f-a69cda7de955' User entered 'None (0)'	System	23 Sep 2020 01:33:56
	System	23 Sep 2020 01:33:56

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:49', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6b14a6cb-6c96-49a1-817f-a69cda7de955' User entered 'None (0)'	System	23 Sep 2020 01:33:56
	System	23 Sep 2020 01:33:56

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:50', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6b14a6cb-6c96-49a1-817f-a69cda7de955' User entered 'None (0)'	System	23 Sep 2020 01:33:56
	System	23 Sep 2020 01:33:56

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:52', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6b14a6cb-6c96-49a1-817f-a69cda7de955' User entered 'No (N)'	System	23 Sep 2020 01:33:56
	System	23 Sep 2020 01:33:56

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-09-22T21:33:54', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '6b14a6cb-6c96-49a1-817f-a69cda7de955' User entered '22 Sep 2020 21:33'	System	23 Sep 2020 01:33:56
	System	23 Sep 2020 01:33:56

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:57:17

US3222143

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:57:17

US3222143

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:43:24

US3222143

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '23 Sep 2020'	Alicia Cevera (b) (4)	15 Oct 2020 14:43:24

US3222143

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:43:24

US3222143

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:43:24

US3222143

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:43:29

US3222143

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	15 Oct 2020 14:43:29

US3222143

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	15 Oct 2020 14:44:18

US3222143

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '30 Sep 2020'	Alicia Cevera (b) (4)	15 Oct 2020 14:44:18

US3222143

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:44:18

US3222143

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:44:18

US3222143

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:44:27

US3222143

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	15 Oct 2020 14:44:27

US3222143

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:49:39

US3222143

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '7 Oct 2020'	Alicia Cevera (b) (4)	15 Oct 2020 14:49:39

US3222143

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:49:39

US3222143

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:49:39

US3222143

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:49:45

US3222143

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	15 Oct 2020 14:49:45

US3222143

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:01

US3222143

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '15 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:01

US3222143

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Clinic (Clinic)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:01

US3222143

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'VISIT3'	System	15 Oct 2020 14:50:01

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Alicia Cevera (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	Alicia Cevera (b) (4)	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered empty.	System	15 Oct 2020 14:50:09

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30

US3222143

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30

US3222143

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:15

US3222143

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:50:15

US3222143

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:55:53

US3222143

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '15 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:55:53

US3222143

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered '10:09'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:55:53

US3222143

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered '15 Oct 2020 10:09'	System	15 Oct 2020 14:55:53

US3222143

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:09
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 14:55:59

US3222143

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	15 Oct 2020 14:55:59

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 64'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 71'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-10-21T09:16:53', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '615ac887-98b4-45b8-996f-06a13c0e5723'	System	21 Oct 2020 13:17:01
User entered 'No (N)'	System	21 Oct 2020 13:17:01

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-10-21T09:16:56', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '615ac887-98b4-45b8-996f-06a13c0e5723'	System	21 Oct 2020 13:17:01
User entered 'No (N)'	System	21 Oct 2020 13:17:01

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-10-21T09:16:59', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '615ac887-98b4-45b8-996f-06a13c0e5723' User entered '21 Oct 2020 09:16:59'	System	21 Oct 2020 13:17:01
	System	21 Oct 2020 13:17:01

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 78'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-10-29T06:05:20', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'feaceac5-51d9-4c20-9b18-7c4de0cd1965'	System	29 Oct 2020 10:05:28
User entered 'No (N)'	System	29 Oct 2020 10:05:28

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-10-29T06:05:22', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'feaceac5-51d9-4c20-9b18-7c4de0cd1965'	System	29 Oct 2020 10:05:28
User entered 'No (N)'	System	29 Oct 2020 10:05:28

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-10-29T06:05:25', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'feaceac5-51d9-4c20-9b18-7c4de0cd1965' User entered '29 Oct 2020 06:05:25'	System	29 Oct 2020 10:05:28
	System	29 Oct 2020 10:05:28

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 92'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-11-15T21:17:46', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7ecc1630-ec09-4e43-a7be-dee1f3554e7a' User entered 'No (N)'	System	16 Nov 2020 02:17:54
	System	16 Nov 2020 02:17:54

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-11-15T21:17:49', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7ecc1630-ec09-4e43-a7be-dee1f3554e7a' User entered 'No (N)'	System	16 Nov 2020 02:17:54
	System	16 Nov 2020 02:17:54

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-11-15T21:17:51', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7ecc1630-ec09-4e43-a7be-dee1f3554e7a' User entered '15 Nov 2020 21:17:51'	System	16 Nov 2020 02:17:54
	System	16 Nov 2020 02:17:54

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:24:36
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11
Data entry locked.	System	14 Aug 2020 15:56:13
User entered 'Day 99'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 15:56:13

US3222143

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:20:11
Data entry locked.	System	14 Aug 2020 15:56:13
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 15:56:13

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-11-24T23:19:21', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a02fa5a5-75e1-4cd6-bbd3-56e0dd5c54fc'	System	25 Nov 2020 04:19:29
User entered 'No (N)'	System	25 Nov 2020 04:19:29

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-11-24T23:19:24', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a02fa5a5-75e1-4cd6-bbd3-56e0dd5c54fc'	System	25 Nov 2020 04:19:29
User entered 'No (N)'	System	25 Nov 2020 04:19:29

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-11-24T23:19:26', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a02fa5a5-75e1-4cd6-bbd3-56e0dd5c54fc'	System	25 Nov 2020 04:19:29
User entered '24 Nov 2020 23:19:26'	System	25 Nov 2020 04:19:29

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-01T11:55:09', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef01dbdd-f12b-41d8-b711-44321597a125'	System	01 Dec 2020 16:55:18
User entered 'No (N)'	System	01 Dec 2020 16:55:18

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-01T11:55:13', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef01dbdd-f12b-41d8-b711-44321597a125'	System	01 Dec 2020 16:55:18
User entered 'No (N)'	System	01 Dec 2020 16:55:18

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-01T11:55:15', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'ef01dbdd-f12b-41d8-b711-44321597a125' User entered '01 Dec 2020 11:55:15'	System	01 Dec 2020 16:55:18
	System	01 Dec 2020 16:55:18

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-06T13:34:55', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e129ffb2-1274-44fd-ba58-9cf94900385f' User entered 'Yes (Y)'	System	06 Dec 2020 18:35:12
	System	06 Dec 2020 18:35:12

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-06T13:34:58', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e129ffb2-1274-44fd-ba58-9cf94900385f' User entered 'No (N)'	System	06 Dec 2020 18:35:12
	System	06 Dec 2020 18:35:12

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-06T13:35:01', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e129ffb2-1274-44fd-ba58-9cf94900385f' User entered 'No (N)'	System	06 Dec 2020 18:35:12
	System	06 Dec 2020 18:35:12

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-06T13:35:05', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e129ffb2-1274-44fd-ba58-9cf94900385f' User entered 'No (N)'	System	06 Dec 2020 18:35:12
	System	06 Dec 2020 18:35:12

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-06T13:35:09', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e129ffb2-1274-44fd-ba58-9cf94900385f' User entered '06 Dec 2020 13:35:09'	System	06 Dec 2020 18:35:12
	System	06 Dec 2020 18:35:12

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-13T08:34:04', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95535efc-4718-4237-8226-6cf55c1441cd' User entered 'Yes (Y)'	System	13 Dec 2020 13:34:37
	System	13 Dec 2020 13:34:37

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-13T08:34:07', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95535efc-4718-4237-8226-6cf55c1441cd' User entered 'Yes (Y)'	System	13 Dec 2020 13:34:37
	System	13 Dec 2020 13:34:37

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Please 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-13T08:34:15', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95535efc-4718-4237-8226-6cf55c1441cd'	System	13 Dec 2020 13:34:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 13:34:37

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-13T08:34:19', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95535efc-4718-4237-8226-6cf55c1441cd' User entered 'No (N)'	System	13 Dec 2020 13:34:37

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-13T08:34:23', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95535efc-4718-4237-8226-6cf55c1441cd' User entered 'Yes (Y)'	System	13 Dec 2020 13:34:37
	System	13 Dec 2020 13:34:37

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Please 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-13T08:34:25', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95535efc-4718-4237-8226-6cf55c1441cd'	System	13 Dec 2020 13:34:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 13:34:37

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-13T08:34:28', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95535efc-4718-4237-8226-6cf55c1441cd' User entered '13 Dec 2020 08:34:28'	System	13 Dec 2020 13:34:37
	System	13 Dec 2020 13:34:37

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-21T12:52:38', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'efaa36e5-135c-463c-8089-48982bed3348' User entered 'No (N)'	System	21 Dec 2020 17:52:46
	System	21 Dec 2020 17:52:46

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-21T12:52:40', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'efaa36e5-135c-463c-8089-48982bed3348' User entered 'No (N)'	System	21 Dec 2020 17:52:46

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-21T12:52:42', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'efaa36e5-135c-463c-8089-48982bed3348' User entered '21 Dec 2020 12:52:42'	System	21 Dec 2020 17:52:46
	System	21 Dec 2020 17:52:46

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-28T10:58:26', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e9b70dab-f823-4422-9936-f25dd95e2c74' User entered 'No (N)'	System	28 Dec 2020 15:58:33
	System	28 Dec 2020 15:58:33

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-28T10:58:28', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e9b70dab-f823-4422-9936-f25dd95e2c74'	System	28 Dec 2020 15:58:33
User entered 'No (N)'	System	28 Dec 2020 15:58:33

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2020-12-28T10:58:30', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'e9b70dab-f823-4422-9936-f25dd95e2c74' User entered '28 Dec 2020 10:58:30'	System	28 Dec 2020 15:58:33
	System	28 Dec 2020 15:58:33

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-03T21:35:24', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7ffdc0c5-a540-4274-bd35-8603e117fe0c'	System	04 Jan 2021 02:35:31
User entered 'No (N)'	System	04 Jan 2021 02:35:31

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-03T21:35:26', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7ffdc0c5-a540-4274-bd35-8603e117fe0c'	System	04 Jan 2021 02:35:31
User entered 'No (N)'	System	04 Jan 2021 02:35:31

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-03T21:35:29', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '7ffdc0c5-a540-4274-bd35-8603e117fe0c' User entered '03 Jan 2021 21:35:29'	System	04 Jan 2021 02:35:31

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-11T22:02:45', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a3ce723a-c54c-45a0-b5d0-e0ea0681f29a'	System	12 Jan 2021 03:02:57
User entered 'No (N)'	System	12 Jan 2021 03:02:57

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-11T22:02:49', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a3ce723a-c54c-45a0-b5d0-e0ea0681f29a'	System	12 Jan 2021 03:02:57
User entered 'No (N)'	System	12 Jan 2021 03:02:57

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-11T22:02:51', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'a3ce723a-c54c-45a0-b5d0-e0ea0681f29a' User entered '11 Jan 2021 22:02:51'	System	12 Jan 2021 03:02:57
	System	12 Jan 2021 03:02:57

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-20T13:54:13', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2d25dc22-c895-409d-8867-143a3f6cbce3' User entered 'No (N)'	System	20 Jan 2021 18:54:22
	System	20 Jan 2021 18:54:22

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-20T13:54:15', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2d25dc22-c895-409d-8867-143a3f6cbce3' User entered 'No (N)'	System	20 Jan 2021 18:54:22
	System	20 Jan 2021 18:54:22

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-20T13:54:17', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '2d25dc22-c895-409d-8867-143a3f6cbce3' User entered '20 Jan 2021 13:54:17'	System	20 Jan 2021 18:54:22
	System	20 Jan 2021 18:54:22

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-24T21:02:54', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9bf48119-501a-48c0-a8d3-772a142510e2' User entered 'No (N)'	System	25 Jan 2021 02:04:19
	System	25 Jan 2021 02:04:19

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-24T21:02:56', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9bf48119-501a-48c0-a8d3-772a142510e2'	System	25 Jan 2021 02:04:19
User entered 'No (N)'	System	25 Jan 2021 02:04:19

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-01-24T21:02:58', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '9bf48119-501a-48c0-a8d3-772a142510e2' User entered '24 Jan 2021 21:02:58'	System	25 Jan 2021 02:04:19

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-09T13:56:28', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b4ea9a8-659e-46f0-89ab-7fedbd8840df' User entered 'No (N)'	System	09 Feb 2021 18:56:36

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-09T13:56:29', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b4ea9a8-659e-46f0-89ab-7fedbd8840df' User entered 'No (N)'	System	09 Feb 2021 18:56:36

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-09T13:56:31', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '3b4ea9a8-659e-46f0-89ab-7fedbd8840df' User entered '09 Feb 2021 13:56:31'	System	09 Feb 2021 18:56:36
	System	09 Feb 2021 18:56:36

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-16T08:21:45', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '0dac4264-af9d-484a-820a-7760b747469f' User entered 'No (N)'	System	16 Feb 2021 13:21:53
	System	16 Feb 2021 13:21:53

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-16T08:21:47', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '0dac4264-af9d-484a-820a-7760b747469f' User entered 'No (N)'	System	16 Feb 2021 13:21:53
	System	16 Feb 2021 13:21:53

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-16T08:21:49', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '0dac4264-af9d-484a-820a-7760b747469f' User entered '16 Feb 2021 08:21:49'	System	16 Feb 2021 13:21:53
	System	16 Feb 2021 13:21:53

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-21T12:47:32', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '1e7ae7a0-84ff-4273-a356-4897e1d57b91' User entered 'No (N)'	System	21 Feb 2021 17:47:39
	System	21 Feb 2021 17:47:39

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-21T12:47:34', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '1e7ae7a0-84ff-4273-a356-4897e1d57b91' User entered 'No (N)'	System	21 Feb 2021 17:47:39
	System	21 Feb 2021 17:47:39

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-02-21T12:47:36', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '1e7ae7a0-84ff-4273-a356-4897e1d57b91' User entered '21 Feb 2021 12:47:36'	System	21 Feb 2021 17:47:39
	System	21 Feb 2021 17:47:39

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-10T20:50:42-05:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95b6385a-402a-4ec3-b0d0-3b37a3d41f4b' User entered 'No (N)'	System	11 Mar 2021 01:50:50
	System	11 Mar 2021 01:50:50

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-10T20:50:44-05:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95b6385a-402a-4ec3-b0d0-3b37a3d41f4b' User entered 'No (N)'	System	11 Mar 2021 01:50:50
	System	11 Mar 2021 01:50:50

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-10T20:50:46-05:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '95b6385a-402a-4ec3-b0d0-3b37a3d41f4b' User entered '10 Mar 2021 20:50:46'	System	11 Mar 2021 01:50:50
	System	11 Mar 2021 01:50:50

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-16T10:07:54-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '303904ae-b1b1-40c0-9e9a-b11b3fc3061b' User entered 'No (N)'	System	16 Mar 2021 14:08:02
	System	16 Mar 2021 14:08:02

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-16T10:07:56-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '303904ae-b1b1-40c0-9e9a-b11b3fc3061b' User entered 'No (N)'	System	16 Mar 2021 14:08:02
	System	16 Mar 2021 14:08:02

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-16T10:07:58-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '303904ae-b1b1-40c0-9e9a-b11b3fc3061b' User entered '16 Mar 2021 10:07:58'	System	16 Mar 2021 14:08:02
	System	16 Mar 2021 14:08:02

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-24T09:37:37-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'daddf208-dff1-4923-be04-441c6add22aa'	System	24 Mar 2021 13:37:45
User entered 'No (N)'	System	24 Mar 2021 13:37:45

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-24T09:37:39-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'daddf208-dff1-4923-be04-441c6add22aa'	System	24 Mar 2021 13:37:45
User entered 'No (N)'	System	24 Mar 2021 13:37:45

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-24T09:37:41-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'daddf208-dff1-4923-be04-441c6add22aa' User entered '24 Mar 2021 09:37:41'	System	24 Mar 2021 13:37:45
	System	24 Mar 2021 13:37:45

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-30T18:58:51-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '362c1d32-3e5a-4c5c-831e-8dede566f8fe' User entered 'No (N)'	System	08 Apr 2021 01:51:17

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-30T18:58:52-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '362c1d32-3e5a-4c5c-831e-8dede566f8fe' User entered 'No (N)'	System	08 Apr 2021 01:51:17

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-30T18:58:55-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '362c1d32-3e5a-4c5c-831e-8dede566f8fe' User entered '30 Mar 2021 18:58:55'	System	08 Apr 2021 01:51:17

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-04-07T21:51:14-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'd3500ec0-8b3c-4104-8758-a7b7afd2d49e'	System	08 Apr 2021 01:51:22
User entered 'No (N)'	System	08 Apr 2021 01:51:22

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-04-07T21:51:16-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'd3500ec0-8b3c-4104-8758-a7b7afd2d49e' User entered 'No (N)'	System	08 Apr 2021 01:51:22
	System	08 Apr 2021 01:51:22

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-04-07T21:51:18-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: 'd3500ec0-8b3c-4104-8758-a7b7afd2d49e' User entered '07 Apr 2021 21:51:18'	System	08 Apr 2021 01:51:22
	System	08 Apr 2021 01:51:22

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-04-13T10:42:14-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '51148d2d-5c27-4642-acf9-95c8605187ab' User entered 'No (N)'	System	13 Apr 2021 14:42:21
	System	13 Apr 2021 14:42:21

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

Have you been exposed to someone with 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 (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-04-13T10:42:15-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '51148d2d-5c27-4642-acf9-95c8605187ab' User entered 'No (N)'	System	13 Apr 2021 14:42:21
	System	13 Apr 2021 14:42:21

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-04-13T10:42:18-04:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '51148d2d-5c27-4642-acf9-95c8605187ab'	System	13 Apr 2021 14:42:21
User entered '13 Apr 2021 10:42:18'	System	13 Apr 2021 14:42:21

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:20:11

US3222143

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:20:11
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:20:11

US3222143

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:03:40

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-05T16:14:30-05:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '17f79023-231c-45be-899b-ce5ebc9c9691'	System	05 Mar 2021 21:53:14
User entered 'No (N)'	System	05 Mar 2021 21:53:14

US3222143

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:03:40

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEA36A94-BD12-4E2C-99B1-9E17FF952912)', Time: '2021-03-05T16:14:33-05:00', User OID: 'PatientReportedOutcome (US3222143)', ODM File OID: '17f79023-231c-45be-899b-ce5ebc9c9691' User entered '05 Mar 2021 16:14:33'	System	05 Mar 2021 21:53:14
	System	05 Mar 2021 21:53:14

US3222143

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:13:21

US3222143

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	11 Jan 2021 21:14:04
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	11 Jan 2021 21:14:04
User entered '9 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 21:14:04
User entered '1 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 21:13:48
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Jan 2021 21:13:21
User entered '11 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 21:13:21

US3222143

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:13:21

US3222143

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:13:21

US3222143

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:14:10

US3222143

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:08:30
User entered 'I'	System	11 Jan 2021 21:14:10

US3222143

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:14:34

US3222143

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:14:34

US3222143

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:14:34

US3222143

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:14:34

US3222143

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:14:48

US3222143

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User entered 'I'	System	11 Jan 2021 21:14:48

US3222143

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:15:12

US3222143

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:15:12

US3222143

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:15:12

US3222143

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:15:12

US3222143

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:15:16

US3222143

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User entered 'I'	System	11 Jan 2021 21:15:16

US3222143

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:34:53

US3222143

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '11 Feb 2021' reason for change: Data Entry Error	(b) (4)	11 Feb 2021 18:35:17
User entered '10 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 18:34:53

US3222143

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:34:53

US3222143

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:34:53

US3222143

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:35:20

US3222143

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:26
User entered 'I'	System	11 Feb 2021 18:35:20

US3222143

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:04

US3222143

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:04

US3222143

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[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 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:04

US3222143

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User entered 'VISIT4'	System	10 Mar 2021 16:30:04

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User entered empty.	System	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User entered empty.	System	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User entered empty.	System	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User entered empty.	System	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User entered empty.	System	30 Mar 2021 16:17:42

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21

US3222143

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21

US3222143

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:15

US3222143

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:15

US3222143

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:33

US3222143

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:33

US3222143

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '11:00'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:33

US3222143

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User entered '10 Mar 2021 11:00'	System	10 Mar 2021 16:30:33

US3222143

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:30:47

US3222143

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:44:21
User entered 'I'	System	10 Mar 2021 16:30:47

US3222143

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:49:40

US3222143

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:49:40

US3222143

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:49:40

US3222143

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:49:40

US3222143

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:49:44

US3222143

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 12:49:44

US3222143

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	30 Mar 2021 16:50:21
	(b) (4)	

US3222143

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
User entered empty.	douglas winter (b) (4)	30 Mar 2021 16:50:21
	(b) (4)	

US3222143

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 16:50:21

US3222143

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	30 Mar 2021 16:50:21

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User closed query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:19:02
Query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'updated' (Site from DM).	Jennifer Dittman (b) (4) (b) (4)	08 Apr 2021 20:03:34
User opened query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:27:26
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	08 Apr 2021 20:03:28
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 14:59:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 14:59:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 14:59:46
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 16:45:46
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:59:46
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:59:46
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4)	02 Apr 2021 14:59:46
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:59:46
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4)	02 Apr 2021 14:59:46
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:59:46
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:45:46

US3222143

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:40

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:45:46

US3222143

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:03:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:36:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	18 Dec 2020 23:36:06
User entered 'No (N)'	(b) (4)	
	Amber Vasquez (b) (4)	09 Oct 2020 18:10:07
	(b) (4)	

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:50:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:28:38
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:28:33
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:26:47
User entered 'USA-US104-2020-mRNA-1273-P301000026'	System	21 Dec 2020 14:26:07
User entered 'New'	(b) (4), (b) (6)	21 Dec 2020 14:26:07

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:23:37
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms benign (excl mesotheliomas), HLT: Respiratory tract and pleural neoplasms benign NEC, PT: Benign lung neoplasm, LLT: Benign lung neoplasm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:35:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:35:39
Data point term sent to Coder	System	09 Apr 2021 19:12:00
Coding entries removed.	Jennifer Dittman (b) (4) (b) (4)	09 Apr 2021 19:11:32
User entered 'LUNG NODULES Benign' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	09 Apr 2021 19:11:32
User closed query 'PV Query: Thank you for updating the event term however event term included symptom (shortness of breath). Please consider updating the event term to the underlying cause/etiology of the event (lung nodules).' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:53:10
User opened query 'Per DM CLR: Please update the condition to confirm if the Lung Nodule was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:21:52
Query 'PV Query: Thank you for updating the event term however event term included symptom (shortness of breath). Please consider updating the event term to the underlying cause/etiology of the event (lung nodules).' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:06:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 15:05:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 15:05:28
Data point term sent to Coder	System	02 Apr 2021 15:04:33

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Apr 2021 15:04:33
User closed query 'CDM Coding, please split the term (SHORTNESS OF BREATH DUE TO LUNG NODULES) into separate records, as 'SHORTNESS OF BREATH' and 'LUNG NODULES' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	System	02 Apr 2021 15:04:31
Query 'CDM Coding, please split the term (SHORTNESS OF BREATH DUE TO LUNG NODULES) into separate records, as 'SHORTNESS OF BREATH' and 'LUNG NODULES' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'corrected' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 15:04:31
User entered 'LUNG NODULES' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:04:12
User opened query 'PV Query: Thank you for updating the event term however event term included symptom (shortness of breath). Please consider updating the event term to the underlying cause/etiology of the event (lung nodules).' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:57:11
User opened query 'CDM Coding, please split the term (SHORTNESS OF BREATH DUE TO LUNG NODULES) into separate records, as 'SHORTNESS OF BREATH' and 'LUNG NODULES' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:31:30
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:28:26
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'lung nodules - updated' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:47:49
Data point term sent to Coder	System	15 Mar 2021 16:47:37
Coding entries removed.	(b) (4), (b) (6)	15 Mar 2021 16:47:32
User entered 'SHORTNESS OF BREATH due to lung nodules' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 16:47:32

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 20:29:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:40:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:40:51
Data point term sent to Coder	System	18 Dec 2020 23:40:25
User entered 'Shortness of breath'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:33:16
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:34:52
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:34:54
User entered 'No (N)'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:34:56
User entered '11 Dec 2020'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:34:58
User entered empty.	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per MM: please provide final outcome and end date when available. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 00:06:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:29:48
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 23:40:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 23:40:42
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	18 Dec 2020 23:40:42
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 23:40:23
User entered empty.	douglas winter (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). DataPoint Verified.	System	23 Apr 2021 11:56:59
	(b) (4), (b) (6)	22 Apr 2021 14:08:16
User closed query 'Stop date is not entered in the source document, please enter it there.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 14:08:11
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:09:19
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Apr 2021 15:31:15
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	02 Apr 2021 15:31:15
Query 'Stop date is not entered in the source document, please enter it there.' answered with 'updated.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:30:09
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Apr 2021 15:29:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:29:48
User opened query 'Stop date is not entered in the source document, please enter it there.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 18:35:23
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 23:42:31
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	18 Dec 2020 23:42:31
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 23:42:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Dec 2020'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:08:18
User entered empty.	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 00:06:57
User closed query 'Source indicates this is grade 2. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 00:06:56
Query 'Source indicates this is grade 2. Please confirm and revise if necessary.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:06:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:04:12
User opened query 'Source indicates this is grade 2. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 18:40:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:50:52
User closed query 'Source still says No. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 15:50:50
Query 'Source still says No. Please confirm and revise if necessary.' answered with 'source confirmed yes' (Site from CRA).	Diana Toney (b) (4)	27 Apr 2021 15:34:49
User opened query 'Source still says No. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:41:45
User closed query 'Source indicates this is No. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:41:45
Query 'Source indicates this is No. Please confirm and revise if necessary.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:20:12
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		02 Apr 2021 15:07:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:07:13
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	02 Apr 2021 15:04:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:04:12
User opened query 'Source indicates this is No. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 18:40:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Dec 2020 23:41:03
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Dec 2020 23:40:23
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:40:25
User entered '0'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:40:24
User entered '0'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:40:22
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		18 Dec 2020 23:41:03
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		18 Dec 2020 23:41:03
User entered '1' reason for change: Data Entry Error douglas winter	(b) (4)	18 Dec 2020 23:41:03
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	18 Dec 2020 23:40:23
User entered '0'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:40:20
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)	12 Apr 2021 16:07:22
User entered '11 Dec 2020'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 15:51:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:50:58
User entered '12 Dec 2020'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:51:00
User entered 'No (N)'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 18:39:52
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:39:50
User entered empty.	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:51:03
User entered '0'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:51:04
User entered '0'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:51:10
User entered '0'	douglas winter (b) (4)	18 Dec 2020 23:40:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:39:44
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:39:46
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:51:09
User closed query 'Source still says None. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 15:51:07
Query 'Source still says None. Please confirm and revise if necessary.' answered with 'action is none' (Site from CRA).	Diana Toney (b) (4)	27 Apr 2021 15:35:02
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4)	27 Apr 2021 15:34:22
User opened query 'Source still says None. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:39:37
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 16 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:20:08
Query 'PV Query: As the last dose of mRNA-1273 was given on 16 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' answered with 'UPDATED AS NOT APPLICABLE' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 18:00:35
DataPoint Un-verified.	douglas winter (b) (4)	23 Apr 2021 11:56:59
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Apr 2021 11:56:59
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 16 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:07:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 00:07:07
User closed query 'Source indicates this is None. Please confirm and respond if necessary.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 00:07:06
Query 'Source indicates this is None. Please confirm and respond if necessary.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:20:26
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:04:12
User opened query 'Source indicates this is None. Please confirm and respond if necessary.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 18:40:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 18:39:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:39:40
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:45
User closed query 'None is ticked on the AE source, however, if subject was in hospital and was diagnosed with lung nodules, there may be conmeds or procedures to report following review of medical records.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:02:42
Query 'None is ticked on the AE source, however, if subject was in hospital and was diagnosed with lung nodules, there may be conmeds or procedures to report following review of medical records.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:34:17
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Apr 2021 15:32:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Apr 2021 15:26:06
User opened query 'None is ticked on the AE source, however, if subject was in hospital and was diagnosed with lung nodules, there may be conmeds or procedures to report following review of medical records.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 18:39:30
User entered '0'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

US3222143

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:39:06
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 10:28:19
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.'	(b) (4), (b) (6)	02 Apr 2021 15:26:31
answered with 'none documented' (Site from DM). User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:26:06
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:09:34
User entered '1'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:39:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:32:25
User entered '0'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Source still says Unknown. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:39:26
User closed query 'This is not entered on the AE form in source. Please enter it there if correct.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:39:26
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	23 Apr 2021 11:56:59
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Apr 2021 11:56:59
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:08:09
Query 'This is not entered on the AE form in source. Please enter it there if correct.' answered with 'updated AE form. At the visit on 3/10/21 patient still c/o SOB d/t lung nodules. requesting hospital DC records.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:33:46
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	02 Apr 2021 15:31:15
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 15:31:15
User opened query 'This is not entered on the AE form in source. Please enter it there if correct.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 18:37:35
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:42:31
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:42:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:27:24
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	18 Dec 2020 23:45:04
User entered 'Diagnosed with unclassified lung nodules.' reason for change: Data Entry Error	douglas winter (b) (4)	18 Dec 2020 23:45:04
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	18 Dec 2020 23:42:31
User entered empty.	douglas winter (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:27:25
User closed query 'PV Query: Are there any prior history of lung nodules or other lung disease? Thank you.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:53:23
Query 'PV Query: Are there any prior history of lung nodules or other lung disease? Thank you.' answered with 'none documented' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:27:06
User opened query 'PV Query: Are there any prior history of lung nodules or other lung disease? Thank you.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:56:36
User opened query 'Per DM CLR: Narrative indicates that the subject had Chest CT. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:10:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 20:30:23
User opened query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 20:30:05
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 20:28:51
User opened 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)	23 Dec 2020 20:28:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'The patient was called after receiving an e-diary alert. I spoke with her today at 08:40 am. She was admitted to the ER for shortness of breath. They did a chest CT and found nodules. I will request medical records..'	douglas winter (b) (4) (b) (4)	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 15:07:13
User entered '0'	System	02 Apr 2021 15:04:12
User entered '1'	System	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Dec 2020 23:40:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Dec 2020 23:40:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:36:12
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:12:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:21:01
User closed query 'Per ETRTR: Other action taken for SAE "SHORTNESS OF BREATH" is Concomitant Medication however medication for this event is not present yet. Please update.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:20:59
User closed query 'Per CDM: Response noted however, CM#1 TYLENOL for HEADACHE corresponds with Diary Dose 2 Day 4, Headache (General) only and there is no corresponding CM recorded for Diary Dose 2 Day 2, Pain at Injection Site and Day 5, Headache (General)? Please reconcile and update to record the medication given ensuring dates/indications correspond.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 11:44:06
Query 'Per CDM: Response noted however, CM#1 TYLENOL for HEADACHE corresponds with Diary Dose 2 Day 4, Headache (General) only and there is no corresponding CM recorded for Diary Dose 2 Day 2, Pain at Injection Site and Day 5, Headache (General)? Please reconcile and update to record the medication given ensuring dates/indications correspond.' answered with 'Day 5 addressed on CM logline 1, updated CM for Diary dose 2 day 2' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:17:50
Query 'Per ETRTR: Other action taken for SAE "SHORTNESS OF BREATH" is Concomitant Medication however medication for this event is not present yet. Please update.' answered with 'no medication documented in source' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:54:15

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Response noted however, CM#1 TYLENOL for HEADACHE corresponds with Diary Dose 2 Day 4, Headache (General) only and there is no corresponding CM recorded for Diary Dose 2 Day 2, Pain at Injection Site and Day 5, Headache (General)? Please reconcile and update to record the medication given ensuring dates/indications correspond.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:52:09
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:52:09
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Tylenol use has been entered into CM page for post dose 2 use. ' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	06 Mar 2021 14:31:25
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 06:27:16
User opened query 'Per ETRTR: Other action taken for SAE "SHORTNESS OF BREATH" is Concomitant Medication however medication for this event is not present yet. Please update.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 14:24:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Diary Dose 2, Log Lines 3 and 4, diary reports medication was taken for pain or fever and previous query response states 'Grade 2. Took 220 mg Aleve for site injection pain.' however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 23:52:59
Query 'Per CDM: Diary Dose 2, Log Lines 3 and 4, diary reports medication was taken for pain or fever and previous query response states 'Grade 2. Took 220 mg Aleve for site injection pain.' however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' answered with 'PLEASE DISREGARD THAT ENTRY. PER SUBJECT SOURCE CHART, SUBJECT TOOK TYLENOL q6h FOR HEADACHE PAIN. THIS IS NOTED ON THE DAY 36 SOURCE DOCUMENT AS WELL AS IN THE CONMED PAGE. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Nov 2020 12:56:51
User opened query 'Per CDM: Diary Dose 2, Log Lines 3 and 4, diary reports medication was taken for pain or fever and previous query response states 'Grade 2. Took 220 mg Aleve for site injection pain.' however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:38:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:12:59

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 12:58:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 12:58:45
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	12 Nov 2020 12:58:21 12 Nov 2020 12:57:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:16:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:16:45
Data point term sent to Coder	System	07 Oct 2020 14:32:50
Data point term sent to Coder	System	07 Oct 2020 14:24:34
User entered 'tylenol'	(b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Oct 2020 14:29:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 14:29:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:29:24
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 14:23:56
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User closed query 'Per DM CLR: Please note that there is no AE/Diary entry 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 appropriate eCRF/s. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 10:40:55
Query 'Per DM CLR: Please note that there is no AE/Diary entry 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 appropriate eCRF/s. Otherwise, provide clarification.	Amber Vasquez (b) (4) (b) (4)	06 Mar 2021 14:20:20
' answered with 'Day 36 safety phone call, subject reported use of Tylenol for headache which resolved 24 hours post injection.' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE/Diary entry 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 appropriate eCRF/s. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:41:26
User entered 'HEADACHE' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Nov 2020 12:57:27
User entered 'taken for headache that lasted 24 hours'	(b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '650'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Oct 2020 14:31:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 14:31:58
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:31:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 14:23:56
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:23:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:15:30
User entered '20 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 20:15:30
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:23:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User entered '4'	System	07 Oct 2020 14:23:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User entered '1'	System	07 Oct 2020 14:23:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:03:48
User entered '804 (804)'	System	07 Oct 2020 14:23:56

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 00:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:11:45
Data point term sent to Coder	System	02 Nov 2020 14:05:23
User entered 'ALPRAZOLAM'	(b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'ANXIETY'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '0.5'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Mar 2021 20:24:59
User entered 'Other (OTHER)'	(b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User closed query 'Per CDM: Response noted however, the unit recorded 'MG' is an available option from the drop down menu for the 'Dose unit' field. Please update 'Dose unit' and 'If dose unit is Other, specify' appropriately. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 11:16:13
Query 'Per CDM: Response noted however, the unit recorded 'MG' is an available option from the drop down menu for the 'Dose unit' field. Please update 'Dose unit' and 'If dose unit is Other, specify' appropriately. Thank you' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 20:27:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 20:24:59
User opened query 'Per CDM: Response noted however, the unit recorded 'MG' is an available option from the drop down menu for the 'Dose unit' field. Please update 'Dose unit' and 'If dose unit is Other, specify' appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:45:48
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:45:48
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'data entry error corrected' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	06 Mar 2021 14:21:51
User entered 'Mg' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	06 Mar 2021 14:21:35
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 22:43:32
User entered 'M'	(b) (4), (b) (6)	02 Nov 2020 14:04:29

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'UN Apr 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 14:04:29

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 00:11:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:11:55
Data point term sent to Coder	System	02 Nov 2020 14:05:26
User entered 'AMITRIPTYLINE'	(b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'ANXIETY'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '25'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'UN Mar 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 14:05:10

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: LOESTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 00:22:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 00:22:13
Data point term sent to Coder	System	02 Nov 2020 14:06:28
User entered 'LOESTRIN'	(b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'BIRTH CONTROL'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 14:06:05

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 15:35:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 15:35:13
Data point term sent to Coder	System	24 Nov 2020 15:34:00
User entered 'flu vaccine'	(b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4)	08 Mar 2021 08:36:47
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	Amber Vasquez (b) (4)	06 Mar 2021 14:23:19
' answered with 'data entry error corrected ' (Site from DM).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Amber Vasquez (b) (4)	06 Mar 2021 14:22:40
	(b) (4)	
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	22 Dec 2020 22:58:52
' (Site from DM).		
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'vaccine'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '0.5'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User entered empty.	System	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User entered empty.	System	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:04:05
User entered empty.	System	24 Nov 2020 15:33:37

US3222143

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:03:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 18:10:17
	(b) (4)	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'USA-US104-2020-MRNA-1273-P301000026'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Bruce'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Teresa'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Rankin'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Becker'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '860 Peachwood Ave'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Deland'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Houston'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 19:30:26
User entered empty.	System	23 Apr 2021 19:30:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 19:20:31
User entered 'FL'	douglas winter (b) (4)	23 Apr 2021 11:51:46
	(b) (4)	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '32720'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '77081'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:29:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'US'	(b) (4) System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	27 Apr 2021 18:21:18
User entered '5'	System	23 Apr 2021 19:30:26
User entered '4'	System	12 Apr 2021 17:27:51
User entered '3'	System	05 Apr 2021 15:54:04
User entered '2'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
	(b) (4)	
User entered '1'	System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'USA-US104-2020-MRNA-1273-P301000026'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Bruce'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Teresa'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Rankin'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Becker'	(b) (4), (b) (6)	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '860 Peachwood Ave'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Deland'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Houston'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 19:30:26
User entered empty.	System	23 Apr 2021 19:30:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 19:20:31
User entered 'FL'	douglas winter (b) (4)	23 Apr 2021 11:51:46
	(b) (4)	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '32720'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '77081'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:29:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'US'	(b) (4) System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	27 Apr 2021 18:21:18
User entered '5'	System	23 Apr 2021 19:30:26
User entered '4'	System	12 Apr 2021 17:27:51
User entered '3'	System	05 Apr 2021 15:54:04
User entered '2'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
	(b) (4)	
User entered '1'	System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:03:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered '21/Dec/2020 06:27'	(b) (4) System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:03:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:29:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'USA-US104-2020-MRNA-1273-P301000026'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Bruce'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Teresa'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Rankin'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Becker'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '860 Peachwood Ave'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Deland'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Houston'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 19:30:26
User entered empty.	System	23 Apr 2021 19:30:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 19:20:31
User entered 'FL'	douglas winter (b) (4)	23 Apr 2021 11:51:46
	(b) (4)	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '32720'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '77081'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:29:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'US'	(b) (4) System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	27 Apr 2021 18:21:18
User entered '5'	System	23 Apr 2021 19:30:26
User entered '4'	System	12 Apr 2021 17:27:51
User entered '3'	System	05 Apr 2021 15:54:04
User entered '2'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
	(b) (4)	
User entered '1'	System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:03:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered '16/Mar/2021 09:29'	(b) (4) System	16 Mar 2021 13:29:24

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:03:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:29:24

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'USA-US104-2020-MRNA-1273-P301000026'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Bruce'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Teresa'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Rankin'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Becker'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '860 Peachwood Ave'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Deland'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Houston'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 19:30:26
User entered empty.	System	23 Apr 2021 19:30:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 19:20:31
User entered 'FL'	douglas winter (b) (4)	23 Apr 2021 11:51:46
	(b) (4)	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '32720'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '77081'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:29:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'US'	(b) (4) System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	27 Apr 2021 18:21:18
User entered '5'	System	23 Apr 2021 19:30:26
User entered '4'	System	12 Apr 2021 17:27:51
User entered '3'	System	05 Apr 2021 15:54:04
User entered '2'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
	(b) (4)	
User entered '1'	System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:03:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered '05/Apr/2021 11:54'	(b) (4) System	05 Apr 2021 15:54:04

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:03:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 17:27:30
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 15:54:04

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'USA-US104-2020-MRNA-1273-P301000026'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Bruce'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Teresa'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Rankin'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Becker'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '860 Peachwood Ave'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Deland'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Houston'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 19:30:26
User entered empty.	System	23 Apr 2021 19:30:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 19:20:31
User entered 'FL'	douglas winter (b) (4)	23 Apr 2021 11:51:46
	(b) (4)	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '32720'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '77081'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:29:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'US'	(b) (4) System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	27 Apr 2021 18:21:18
User entered '5'	System	23 Apr 2021 19:30:26
User entered '4'	System	12 Apr 2021 17:27:51
User entered '3'	System	05 Apr 2021 15:54:04
User entered '2'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
	(b) (4)	
User entered '1'	System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:03:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered '12/Apr/2021 13:27'	(b) (4) System	12 Apr 2021 17:27:51

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:03:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 19:20:31
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 17:27:51

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'USA-US104-2020-MRNA-1273-P301000026'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Bruce'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Teresa'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Rankin'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Becker'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '860 Peachwood Ave'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Deland'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Houston'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 19:30:26
User entered empty.	System	23 Apr 2021 19:30:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 19:20:31
User entered 'FL'	douglas winter (b) (4)	23 Apr 2021 11:51:46
	(b) (4)	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '32720'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '77081'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:29:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'US'	(b) (4) System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	27 Apr 2021 18:21:18
User entered '5'	System	23 Apr 2021 19:30:26
User entered '4'	System	12 Apr 2021 17:27:51
User entered '3'	System	05 Apr 2021 15:54:04
User entered '2'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
	(b) (4)	
User entered '1'	System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:03:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered '23/Apr/2021 15:30'	(b) (4) System	23 Apr 2021 19:30:26

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:03:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:30:26

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'USA-US104-2020-MRNA-1273-P301000026'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'Yes (Y)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:27:07
User entered 'No (N)'	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Bruce'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Teresa'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Rankin'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Becker'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '860 Peachwood Ave'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered 'Deland'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered 'Houston'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:49:50
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 19:30:26
User entered empty.	System	23 Apr 2021 19:30:26
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 19:20:31
User entered 'FL'	douglas winter (b) (4)	23 Apr 2021 11:51:46
	(b) (4)	

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:53:53
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:18:52
Un-reviewed for Safety.	(b) (4)	16 Mar 2021 13:29:24
Signature has been broken.	System	16 Mar 2021 13:29:24
User entered '32720'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
Reviewed for Safety.	(b) (4)	21 Dec 2020 14:27:07
User entered '77081'	(b) (4), (b) (6)	21 Dec 2020 14:26:07
	System	21 Dec 2020 14:26:07

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:29:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
User entered 'US'	(b) (4) System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	27 Apr 2021 18:21:18
User entered '5'	System	23 Apr 2021 19:30:26
User entered '4'	System	12 Apr 2021 17:27:51
User entered '3'	System	05 Apr 2021 15:54:04
User entered '2'	System	16 Mar 2021 13:29:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 17:33:05
	(b) (4)	
User entered '1'	System	21 Dec 2020 14:27:14

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:03:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:12:54
User entered '27/Apr/2021 11:21'	(b) (4) System	27 Apr 2021 18:21:18

US3222143

Folder: SAE USA-US104-2020-MRNA-1273-P301000026

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:03:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:12:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:21:18