

US3922043 (Prod: Synexus Clinical Research US, Inc. - Dallas)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:21:41

All time stamps listed in this document are displayed in GMT

US3922043

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

[Participant ID](#)

US3922043

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

US3922043

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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

Visit date (dd MMM yyyy)	27 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
------------	------

US3922043

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
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	False
Black	True
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

US3922043

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 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

US3922043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3922043

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

[Were any significant conditions reported?](#)

Yes ☒

No ☐

US3922043

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Condition	DIABETES MELLITUS TYPE II
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3922043

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3922043

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3922043

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Condition	NEUROPATHY DIABETIC BILATERAL FEET (SENSORY)
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3922043

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3922043

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Condition	PARTIAL PANCREATECTOMY
Start date (dd MMM yyyy)	UN UNK 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)	UN UNK 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

US3922043

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3922043

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Condition	PANCREATIC MASS (BENIGN)
Start date (dd MMM yyyy)	UN UNK 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)	UN UNK 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

US3922043

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:50 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 12:50
Height (<i>xxx.x</i>)	69.0 in
Weight (<i>xxx.x</i>)	190.0 lb
BMI (<i>xxx.x</i>)	28.11676 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)	

US3922043

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3922043

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*) 27 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*) UN UNK 1999
Date of last menstruation unknown False

US3922043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 144303

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 ☒

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Height	ND - Not Done
Weight	ND - Not Done

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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)	27 AUG 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 12:50
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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)	27 AUG 2020
Time of assessment (00:00-23:59)	17:00 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:00
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3922043

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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.

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 16:29 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 16:29

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

US3922043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 AUG 2020

Collection time (00:00-23:59)

13:15 (24 HR)

Collection date and time (derived)

27 AUG 2020 13:15

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Collection date (<i>dd MMM yyyy</i>)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:17	27 AUG 2020 14:17
Nasopharyngeal Swab 2	No		

US3922043

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 17:08

PC Open Date & Time

27 AUG 2020 16:49

PC Close Date & Time

27 AUG 2020 19:19

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	28 AUG 2020 00:24
PC Open Date & Time	27 AUG 2020 20:14
PC Close Date & Time	28 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

96.2 °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

28 AUG 2020 15:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 14:55

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 13:31

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 17:07

PC Open Date & Time

27 AUG 2020 16:49

PC Close Date & Time

27 AUG 2020 19:19

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

27 AUG 2020 20:14

PC Close Date & Time

28 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

28 AUG 2020 15:10

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

01 SEP 2020 12:23

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

02 SEP 2020 13:33

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 17:09
PC Open Date & Time	27 AUG 2020 16:49
PC Close Date & Time	27 AUG 2020 19:19

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 00:26
PC Open Date & Time	27 AUG 2020 20:14
PC Close Date & Time	28 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

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 ☒

PRODUCTION RELEASE (v12.003

51 of 1953

EAB) (1725)

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 15:09
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

53 of 1953

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 1953

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

Yes ☐

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

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)

57 of 1953

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

Yes ☐

PC Time stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

59 of 1953

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:24
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

61 of 1953

EAB) (1725)

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 13:32
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3922043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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)	28 SEP 2020
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:11
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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)	28 SEP 2020
Time of assessment (00:00-23:59)	12:21 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:21
Temperature (xxx.x)	97.5 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3922043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 11:49 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:49

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

US3922043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

10:19 (24 HR)

Collection date and time (derived)

28 SEP 2020 10:19

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:45	28 SEP 2020 10:45
Nasopharyngeal Swab 2	No		

US3922043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

97.5 °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

28 SEP 2020 12:24

PC Open Date & Time

28 SEP 2020 12:09

PC Close Date & Time

28 SEP 2020 14:39

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	28 SEP 2020 21:22
PC Open Date & Time	28 SEP 2020 15:34
PC Close Date & Time	29 SEP 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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

29 SEP 2020 22:38

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 10:06

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

03 OCT 2020 00:31

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

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

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 12:24

PC Open Date & Time

28 SEP 2020 12:09

PC Close Date & Time

28 SEP 2020 14:39

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 21:26

PC Open Date & Time

28 SEP 2020 15:34

PC Close Date & Time

29 SEP 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

29 SEP 2020 22:40

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 10:08

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 00:32

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 12:25
PC Open Date & Time	28 SEP 2020 12:09
PC Close Date & Time	28 SEP 2020 14:39

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 21:23
PC Open Date & Time	28 SEP 2020 15:34
PC Close Date & Time	29 SEP 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

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 ☒

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 22:41
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

99 of 1953

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

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 ☒

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 10:07
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

103 of 1953

EAB) (1725)

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 00:33
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

105 of 1953

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

107 of 1953

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

Yes ☐

PC Time stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3922043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments SC LEAD LC COMPLETED
SAFETY CALL DAY 36 WITHIN
If Contact Not Made, please provide Comments WINDOW.

US3922043

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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) _____

US3922043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

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.

US3922043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

23 OCT 2020 11:40

US3922043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:30

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 05:34:58

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

05 NOV 2020 10:47:24

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

10 NOV 2020 08:15:43

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 06:36:42

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 96
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	28 NOV 2020 18:22:14
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

06 DEC 2020 22:05:49

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

13 DEC 2020 22:26:22

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 02:10:53

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 12:18:09

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 01:10:35
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

09 JAN 2021 00:03:08

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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	20 JAN 2021 09:29:43
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

23 JAN 2021 23:43:43

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

30 JAN 2021 12:42:26

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

06 FEB 2021 21:36:47

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 02:45:33

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

20 FEB 2021 12:25:49

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 187

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

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

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

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

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

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

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

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 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	15 MAR 2021 12:31:01
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 07:05:04

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

27 MAR 2021 11:22:11

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

03 APR 2021 05:58:24

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 APR 2021 22:31:10
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 APR 2021 19:33:05
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

24 APR 2021 06:54:00

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 <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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 <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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 <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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 <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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Patient Cloud Close Date & Time	29 DEC 2021 23:59
---	-------------------

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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°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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 <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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	17 AUG 2022 23:59
---	-------------------

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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°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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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 <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"/>

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

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

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3922043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:21:41

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		15 MAR 2021 12:32:32

US3922043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 19:23:31

Generated On: 10 Jun 2021 10:21:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922043

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 19:23:31

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 13:01:12

Generated On: 10 Jun 2021 10:21:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 22:06:03

Generated On: 10 Jun 2021 10:21:41

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) _____

US3922043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 13:01:12

Generated On: 10 Jun 2021 10:21:41

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.

US3922043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 13:01:12

Generated On: 10 Jun 2021 10:21:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	15 MAR 2021 12:15

US3922043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 13:01:12

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3922043

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:21:41

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"/>

US3922043

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:21:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3922043

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

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

Visit date (dd MMM yyyy)	05 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3922043

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

Form: Unblinding

Data signed: (b) (4) 11 Mar 2021 21:01:44

Generated On: 10 Jun 2021 10:21:41

Date of updated informed consent (*dd MMM yyyy*) 05 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 05 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3922043

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 FEB 2021

Collection time (00:00-23:59)

10:49 (24 HR)

Collection date and time (derived)

05 FEB 2021 10:49

US3922043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

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

Collection date (dd MMM yyyy)	05 FEB 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	10:57
---------------------------------	-------

Collection Date and Time (derived)	05 FEB 2021 10:57
------------------------------------	-------------------

US3922043

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Apr 2021 21:55:29

Generated On: 10 Jun 2021 10:21:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

AEID	USA-US212-2021-MRNA-1273-P30 1000010
Adverse event	SHORTNESS OF BREATH
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 APR 2021
Hospital Discharge Date (dd MMM yyyy)	14 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

329 of 1953

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

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

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

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

Yes ☒

No ☐

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

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

332 of 1953

EAB) (1725)

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	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 2013	
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"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

334 of 1953

EAB) (1725)

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication SENSORY NEUROPATHY
DIABETIC BILATERAL FEET

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

336 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication JARDAIANCE

Prophylaxis Yes ☐
No ☒

Indication TYPE2 DIABETES

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)

338 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

340 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

342 of 1953

EAB) (1725)

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication PIOGLITAZONE

Prophylaxis Yes ☐
No ☒

Indication TYPE2 DIABESTES

Dose per administration 30

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 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication TRAJENTA

Prophylaxis Yes ☐
No ☒

Indication TYPE2 DIABETES

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication TRIAMTERENE
HYDROCHLOROTHIAZIDE
37.5/25

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication INSULIN ASPART
PROTAMINE/INSULIN ASPART

Prophylaxis Yes ☐
No ☒

Indication TYPE2 DIABETES

Dose per administration 10/60

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	FLU PROPHYLAXIS
------------	-----------------

Dose per administration	0.5
-------------------------	-----

Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

352 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	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)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 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"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication HUMULOG
72-25 KWIK PEN

Prophylaxis Yes ☐
No ☒

Indication TYPE II - DIABETES MELLITUS

Dose per administration 35-25

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

Name of Medication CLOBETASOL PROPIONATE
GEL .05%

Prophylaxis Yes ☐
No ☒

Indication PSORIASIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Feb 2021 20:27:28

Generated On: 10 Jun 2021 10:21:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 20:27:29

Generated On: 10 Jun 2021 10:21:41

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3922043

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:21:41

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 ☐

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 13:58:32

Generated On: 10 Jun 2021 10:21:41

SAEID	USA-US212-2021-MRNA-1273-P301000010
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	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 13:58:32

Generated On: 10 Jun 2021 10:21:41

SAEID	USA-US212-2021-MRNA-1273-P301000010
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	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	23/APR/2021 10:42
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

US3922043 (Prod: Synexus Clinical Research US, Inc. - Dallas)

US3922043

Form: Participant Creation

Generated On: 10 Jun 2021 10:21:41

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'US3922043'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:10:17

US3922043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:14
	(b) (4)	

US3922043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '27 AUG 2020'	RWS_ENDPOINT	27 Aug 2020 17:10:18
	ENDPOINT (b) (4)	

US3922043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Clinic (Clinic)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:14
	(b) (4)	

US3922043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'SCRN'	System	27 Aug 2020 22:00:14

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered (b) (6) 1960'	RWS_ENDPOINT	27 Aug 2020 17:10:19
	ENDPOINT (b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '60'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'YEARS'	System	27 Aug 2020 22:00:34

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '60'	System	27 Aug 2020 22:00:49

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Female (F)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'I'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34
	(b) (4)	

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '27 Aug 2020'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49
	(b) (4)	

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Aug 2020'	System	27 Aug 2020 22:00:49

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2020'	System	27 Aug 2020 22:00:49

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Amendment 2 (2)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49
	(b) (4)	

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49
	(b) (4)	

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49
	(b) (4)	

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49
	(b) (4)	

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49
	(b) (4)	

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	RWS_ENDPOINT	27 Aug 2020 17:10:18
	ENDPOINT (b) (4)	

US3922043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '1'	System	27 Aug 2020 22:00:56

US3922043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:56
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:21:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:53:37
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:08
Data point term sent to Coder	System	22 Feb 2021 20:27:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:54:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:54:47
Data point term sent to Coder	System	02 Sep 2020 23:54:18
User entered 'diabetes mellitus type II'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2013'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:54:14
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2013'	System	02 Sep 2020 23:54:14

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2013'	System	02 Sep 2020 23:54:14

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:54:14

US3922043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:54:14

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:07
Data point term sent to Coder	System	22 Feb 2021 20:27:35
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:55:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:55:48
Data point term sent to Coder	System	02 Sep 2020 23:55:20
User entered 'hypertension'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2003'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:54:25
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2003'	System	02 Sep 2020 23:54:25

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2003'	System	02 Sep 2020 23:54:25

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:54:25

US3922043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:54:25

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:02
Data point term sent to Coder	System	22 Feb 2021 20:27:35
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:55:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:55:47
Data point term sent to Coder	System	02 Sep 2020 23:55:21
User entered 'hypercholesterolemia'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2013'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:55:02
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2013'	System	02 Sep 2020 23:55:02

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2013'	System	02 Sep 2020 23:55:02

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:55:02

US3922043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:55:02

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	22 Feb 2021 20:28:10
Data point term sent to Coder	System	22 Feb 2021 20:27:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:01:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	23 Nov 2020 10:01:29
User closed query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	08 Nov 2020 12:10:04
' (Site from DM).		
Data point term sent to Coder	System	02 Nov 2020 20:16:19
User entered 'NEUROPATHY DIABETIC BILATERAL FEET (sensory)' reason for change:	Pauline Jackson (b) (4)	02 Nov 2020 20:15:37
Data Entry Error	(b) (4)	
Query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Pauline Jackson (b) (4)	02 Nov 2020 20:15:29
' answered with 'subject contacted. explained neuropathy is sensory' (Site from DM).	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor). 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). Data point term sent to Coder Coding entries removed.	(b) (4), (b) (6) (b) (4) System lynn yauch (b) (4) (b) (4)	29 Oct 2020 16:05:34 26 Oct 2020 15:59:19 26 Oct 2020 15:58:34
User entered 'NEUROPATHY diabetic bilateral feet' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	26 Oct 2020 15:58:34
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:55:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder User entered 'neuropathy'	Coder Import (b) (4) (b) (4) System Cristina Puig (b) (4) (b) (4)	02 Sep 2020 23:55:48 02 Sep 2020 23:55:21 02 Sep 2020 23:55:16

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2014'	Cristina Puig (b) (4)	02 Sep 2020 23:55:16
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:16
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:55:16
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:55:16
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:16
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2014'	System	02 Sep 2020 23:55:16

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2014'	System	02 Sep 2020 23:55:16

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:55:16

US3922043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:55:16

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:07
Data point term sent to Coder	System	22 Feb 2021 20:27:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:56:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:56:48
Data point term sent to Coder	System	02 Sep 2020 23:56:22
User entered 'seasonal allergies'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2000'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:55:29
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2000'	System	02 Sep 2020 23:55:29

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2000'	System	02 Sep 2020 23:55:29

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:55:29

US3922043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:55:29

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	22 Feb 2021 20:28:03
Data point term sent to Coder	System	22 Feb 2021 20:27:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 23:56:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	02 Sep 2020 23:56:48
Data point term sent to Coder	System	02 Sep 2020 23:56:23
User entered 'psoriasis'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2015'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:56:19
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2015'	System	02 Sep 2020 23:56:19

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2015'	System	02 Sep 2020 23:56:19

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:56:19

US3922043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	02 Sep 2020 23:56:19

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Pancreatic therapeutic procedures, PT: Pancreatectomy, LLT: Pancreatectomy - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:09
Data point term sent to Coder	System	22 Feb 2021 20:27:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
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) (6)	27 Oct 2020 13:40:54
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 'medical history updated' (Site from DM).	Pauline Jackson (b) (4)	19 Oct 2020 21:26:59
	(b) (4)	
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)	13 Oct 2020 03:06:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Pancreatic therapeutic procedures, PT: Pancreatectomy, LLT: Pancreatectomy - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 09:25:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 09:25:47
Data point term sent to Coder	System	02 Sep 2020 23:58:24
User entered 'partial pancreatectomy'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2013'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2013'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2013'	System	02 Sep 2020 23:57:41

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2013'	System	02 Sep 2020 23:57:41

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2013'	System	02 Sep 2020 23:57:41

US3922043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2013'	System	02 Sep 2020 23:57:41

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 20:28:05
Data point term sent to Coder	System	22 Feb 2021 20:27:37
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:21:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:21:56
Data point term sent to Coder	System	30 Sep 2020 14:20:27
User entered 'post menopausal'	lynn yauch (b) (4)	30 Sep 2020 14:20:04
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 1999'	lynn yauch (b) (4)	30 Sep 2020 14:20:04
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	30 Sep 2020 14:20:04
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	30 Sep 2020 14:20:04
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	30 Sep 2020 14:20:04
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	30 Sep 2020 14:20:04
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 1999'	System	30 Sep 2020 14:20:04

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '1999'	System	30 Sep 2020 14:20:04

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	30 Sep 2020 14:20:04

US3922043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	30 Sep 2020 14:20:04

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Pancreatic disorders NEC, PT: Pancreatic mass, LLT: Pancreatic mass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:05
Data point term sent to Coder	System	22 Feb 2021 20:27:39
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Pancreatic disorders NEC, PT: Pancreatic mass, LLT: Pancreatic mass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:08:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:08:43
Data point term sent to Coder	System	19 Oct 2020 21:27:38
User entered 'pancreatic mass (benign)'	Pauline Jackson (b) (4) (b) (4)	19 Oct 2020 21:26:39

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2013'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 2013'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39
	(b) (4)	

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2013'	System	19 Oct 2020 21:26:39

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2013'	System	19 Oct 2020 21:26:39

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'Jan 2013'	System	19 Oct 2020 21:26:39

US3922043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '2013'	System	19 Oct 2020 21:26:39

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '27 Aug 2020'	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '12:50'	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '27 Aug 2020 12:50'	System	02 Sep 2020 23:59:00

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '69.0' in	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	
DataPoint set to visible.	System	27 Aug 2020 22:00:56

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '190.0' lb	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	
DataPoint set to visible.	System	27 Aug 2020 22:00:56

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '28.11676'	System	02 Sep 2020 23:59:00
DataPoint set to visible.	System	27 Aug 2020 22:00:56

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'kg/m2'	System	02 Sep 2020 23:59:00
DataPoint set to visible.	System	27 Aug 2020 22:00:56

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'bpm'	System	02 Sep 2020 23:59:00

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'breaths/min'	System	02 Sep 2020 23:59:00

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'mmHg'	System	02 Sep 2020 23:59:00

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00
	(b) (4)	

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'mmHg'	System	02 Sep 2020 23:59:00

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 12:08:01

US3922043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 12:08:01

US3922043

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:59:31
	(b) (4)	

US3922043

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '27 Aug 2020'	Cristina Puig (b) (4)	02 Sep 2020 23:59:31
	(b) (4)	

US3922043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '27 Aug 2020'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41
	(b) (4)	

US3922043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41
	(b) (4)	

US3922043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:21:41

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 11:29:08
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'updated MH per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	30 Sep 2020 14:19:42
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 06:43:23
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Cristina Puig (b) (4) (b) (4)	03 Sep 2020 00:01:41

US3922043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:21:41

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:01:41
	(b) (4)	

US3922043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:01:41
	(b) (4)	

US3922043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:21:41

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41
	(b) (4)	

US3922043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'un UNK 1999'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41
	(b) (4)	

US3922043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:21:41

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

[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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

[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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'I'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:02:20
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:01:10

US3922043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '27 Aug 2020'	(b) (4) Patrick Brooks (b) (4)	27 Aug 2020 22:01:10

US3922043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Clinic (Clinic)'	Patrick Brooks (b) (4)	27 Aug 2020 22:01:10

US3922043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'VISIT1'	System	27 Aug 2020 22:01:10

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:24:54

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '144303'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:24:54

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:24:54

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	Patrick Brooks (b) (4)	27 Aug 2020 22:02:00

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	Patrick Brooks (b) (4)	27 Aug 2020 22:02:00

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	Patrick Brooks (b) (4)	27 Aug 2020 22:02:00

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:02:00

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	Patrick Brooks (b) (4)	27 Aug 2020 22:02:00

US3922043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4)	08 Oct 2020 19:35:09
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 09:48:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:16:40

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered missing code ND - Not Done.	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered missing code ND - Not Done.	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered missing code ND - Not Done.	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered missing code ND - Not Done.	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User accepted default value 'Pre-Dose (PREDOSE)'	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '27 Aug 2020'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '12:50'	(b) (4) Cristina Puig (b) (4) (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '27 Aug 2020 12:50'	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 00:03:35
User entered '96.8' F reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:03:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 00:03:07
	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Cristina Puig (b) (4)	03 Sep 2020 00:03:35
User entered empty.	(b) (4)	
	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	03 Sep 2020 00:03:35
data change (Site from System).		03 Sep 2020 00:03:35
User entered '72' reason for change: Data Entry	Cristina Puig (b) (4)	03 Sep 2020 00:03:35
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 00:03:07
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'bpm'	System	03 Sep 2020 00:03:35
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 00:03:35
User entered '15' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:03:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 00:03:07
	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'breaths/min'	System	03 Sep 2020 00:03:35
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 00:03:35
User entered '148' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:03:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 00:03:07
	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'mmHg'	System	03 Sep 2020 00:03:35
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 00:03:35
User entered '88' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:03:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 00:03:07
	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'mmHg'	System	03 Sep 2020 00:03:35
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered missing code ND - Not Done.	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered missing code ND - Not Done.	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User accepted default value 'Post-Dose (POSTDOSE)'	Cristina Puig (b) (4) (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:04:11
User entered '27 Aug 2020' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:04:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:03:07
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Sep 2020 00:04:11
User entered '17:00' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:04:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:03:07
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '27 Aug 2020 17:00'	System	03 Sep 2020 00:04:11
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Sep 2020 00:04:11
User entered '98.6' F reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:04:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:03:07
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Cristina Puig (b) (4)	03 Sep 2020 00:04:11
User entered empty.	(b) (4)	
	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 00:04:11
User entered '69' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:04:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 00:03:07
	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'bpm'	System	03 Sep 2020 00:04:11
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Sep 2020 00:04:11
User entered '16' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:04:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:03:07
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:03:07
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'breaths/min'	System	03 Sep 2020 00:04:11
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Sep 2020 00:04:11
User entered '132' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:04:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:03:07
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'mmHg'	System	03 Sep 2020 00:04:11
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Sep 2020 00:04:11
User entered '89' reason for change: Data Entry Error	Cristina Puig (b) (4)	03 Sep 2020 00:04:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	03 Sep 2020 00:03:07
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'mmHg'	System	03 Sep 2020 00:04:11
User entered empty.	System	03 Sep 2020 00:03:07

US3922043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:04:24

US3922043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:04:24

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) Patrick Brooks (b) (4)	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Patrick Brooks (b) (4)	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '27 Aug 2020'	Patrick Brooks (b) (4)	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '16:29'	Patrick Brooks (b) (4)	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '27 Aug 2020 16:29'	System	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Patrick Brooks (b) (4)	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'ONCE'	System	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 22:02:48

US3922043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:06:25

US3922043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '27 Aug 2020'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:06:25
	(b) (4)	

US3922043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '13:15'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:06:25

US3922043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '27 Aug 2020 13:15'	System	03 Sep 2020 00:06:25

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:21:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '27 Aug 2020'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cristina Puig (b) (4) (b) (4)	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '14:17'	Cristina Puig (b) (4)	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '27 Aug 2020 14:17'	System	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cristina Puig (b) (4) (b) (4)	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered empty.	System	03 Sep 2020 00:06:45

US3922043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Cristina Puig (b) (4)	03 Sep 2020 00:06:54

US3922043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	03 Sep 2020 00:06:54

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:07:21', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'f7d00b57-6caa-4103-ac17-66eb194ba643'	System	27 Aug 2020 22:08:05
User entered 'Yes (Y)'	System	27 Aug 2020 22:08:05

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:07:44', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'f7d00b57-6caa-4103-ac17-66eb194ba643'	System	27 Aug 2020 22:08:05
User entered '96.8'	System	27 Aug 2020 22:08:05

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:07:49', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'f7d00b57-6caa-4103-ac17-66eb194ba643'	System	27 Aug 2020 22:08:05
User entered 'No (N)'	System	27 Aug 2020 22:08:05

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:08:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'f7d00b57-6caa-4103-ac17-66eb194ba643'	System	27 Aug 2020 22:08:05
User entered '27 Aug 2020 17:08'	System	27 Aug 2020 22:08:05

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 16:49'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 19:19'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:24:05', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '2a8d8e4b-052e-48b5-a34f-4c4287d09aeb'	System	28 Aug 2020 05:24:42
User entered 'Yes (Y)'	System	28 Aug 2020 05:24:42

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:24:19', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '2a8d8e4b-052e-48b5-a34f-4c4287d09aeb'	System	28 Aug 2020 05:24:42
User entered '97.5'	System	28 Aug 2020 05:24:42

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:24:26', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '2a8d8e4b-052e-48b5-a34f-4c4287d09aeb'	System	28 Aug 2020 05:24:42
User entered 'No (N)'	System	28 Aug 2020 05:24:42

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:24:38', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '2a8d8e4b-052e-48b5-a34f-4c4287d09aeb'	System	28 Aug 2020 05:24:42
User entered '28 Aug 2020 00:24'	System	28 Aug 2020 05:24:42

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 20:14'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 2'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:07:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'c33ee0dc-2585-4224-85e2-794b2cca05f1'	System	28 Aug 2020 20:07:58
User entered 'Yes (Y)'	System	28 Aug 2020 20:07:58

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:07:18', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'c33ee0dc-2585-4224-85e2-794b2cca05f1'	System	28 Aug 2020 20:07:58
User entered '96.2'	System	28 Aug 2020 20:07:58

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:07:29', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'c33ee0dc-2585-4224-85e2-794b2cca05f1'	System	28 Aug 2020 20:07:58
User entered 'No (N)'	System	28 Aug 2020 20:07:58

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:07:55', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'c33ee0dc-2585-4224-85e2-794b2cca05f1'	System	28 Aug 2020 20:07:58
User entered '28 Aug 2020 15:07'	System	28 Aug 2020 20:07:58

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 3'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 4'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-30T14:54:54', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1e9975d8-9f8d-468a-947a-59de42171e6b'	System	30 Aug 2020 19:55:44
User entered 'Yes (Y)'	System	30 Aug 2020 19:55:44

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-30T14:55:20', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1e9975d8-9f8d-468a-947a-59de42171e6b'	System	30 Aug 2020 19:55:44
User entered '98.3'	System	30 Aug 2020 19:55:44

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-30T14:55:29', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1e9975d8-9f8d-468a-947a-59de42171e6b'	System	30 Aug 2020 19:55:44
User entered 'No (N)'	System	30 Aug 2020 19:55:44

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-30T14:55:40', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1e9975d8-9f8d-468a-947a-59de42171e6b'	System	30 Aug 2020 19:55:44
User entered '30 Aug 2020 14:55'	System	30 Aug 2020 19:55:44

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 5'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 6'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:21:26', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'c22fb249-0ba1-4106-a660-84c1cbf81059'	System	01 Sep 2020 17:22:11
User entered 'Yes (Y)'	System	01 Sep 2020 17:22:11

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:21:42', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'c22fb249-0ba1-4106-a660-84c1cbf81059'	System	01 Sep 2020 17:22:11
User entered '98.6'	System	01 Sep 2020 17:22:11

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:21:55', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'c22fb249-0ba1-4106-a660-84c1cbf81059'	System	01 Sep 2020 17:22:11
User entered 'No (N)'	System	01 Sep 2020 17:22:11

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:22:05', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'c22fb249-0ba1-4106-a660-84c1cbf81059'	System	01 Sep 2020 17:22:11
User entered '01 Sep 2020 12:22'	System	01 Sep 2020 17:22:11

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 7'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:30:51', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'd0304a1f-430b-4d82-be91-b0016ece7c74'	System	02 Sep 2020 18:31:14
User entered 'Yes (Y)'	System	02 Sep 2020 18:31:14

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:30:58', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'd0304a1f-430b-4d82-be91-b0016ece7c74'	System	02 Sep 2020 18:31:14
User entered '96.2'	System	02 Sep 2020 18:31:14

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:31:05', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'd0304a1f-430b-4d82-be91-b0016ece7c74'	System	02 Sep 2020 18:31:14
User entered 'No (N)'	System	02 Sep 2020 18:31:14

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:31:10', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'd0304a1f-430b-4d82-be91-b0016ece7c74'	System	02 Sep 2020 18:31:14
User entered '02 Sep 2020 13:31'	System	02 Sep 2020 18:31:14

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:05:31', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5c432276-9535-4866-a142-e075d133ac48'	System	27 Aug 2020 22:07:13
User entered 'None (1)'	System	27 Aug 2020 22:07:13

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:06:10', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5c432276-9535-4866-a142-e075d133ac48'	System	27 Aug 2020 22:07:13
User entered 'No (N)'	System	27 Aug 2020 22:07:13

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:06:22', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5c432276-9535-4866-a142-e075d133ac48'	System	27 Aug 2020 22:07:13
User entered 'No (N)'	System	27 Aug 2020 22:07:13

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:06:40', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5c432276-9535-4866-a142-e075d133ac48'	System	27 Aug 2020 22:07:13
User entered 'None (1)'	System	27 Aug 2020 22:07:13

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:07:07', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5c432276-9535-4866-a142-e075d133ac48'	System	27 Aug 2020 22:07:13
User entered '27 Aug 2020 17:07'	System	27 Aug 2020 22:07:13

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 16:49'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 19:19'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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)	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 20:14'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 2'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:09:25', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '910f3cb8-3821-474f-848a-8350a492c1c3'	System	28 Aug 2020 20:10:15
User entered 'None (1)'	System	28 Aug 2020 20:10:15

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:09:39', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '910f3cb8-3821-474f-848a-8350a492c1c3'	System	28 Aug 2020 20:10:15
User entered 'No (N)'	System	28 Aug 2020 20:10:15

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:09:48', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '910f3cb8-3821-474f-848a-8350a492c1c3'	System	28 Aug 2020 20:10:15
User entered 'No (N)'	System	28 Aug 2020 20:10:15

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:09:57', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '910f3cb8-3821-474f-848a-8350a492c1c3'	System	28 Aug 2020 20:10:15
User entered 'None (1)'	System	28 Aug 2020 20:10:15

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:10:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '910f3cb8-3821-474f-848a-8350a492c1c3'	System	28 Aug 2020 20:10:15
User entered '28 Aug 2020 15:10'	System	28 Aug 2020 20:10:15

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 3'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 4'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 5'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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)	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 6'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:22:32', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '7cd43267-556d-44b4-9d49-006e6b499097'	System	01 Sep 2020 17:23:12
User entered 'None (1)'	System	01 Sep 2020 17:23:12

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:22:46', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '7cd43267-556d-44b4-9d49-006e6b499097'	System	01 Sep 2020 17:23:12
User entered 'No (N)'	System	01 Sep 2020 17:23:12

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:22:51', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '7cd43267-556d-44b4-9d49-006e6b499097'	System	01 Sep 2020 17:23:12
User entered 'No (N)'	System	01 Sep 2020 17:23:12

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:22:58', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '7cd43267-556d-44b4-9d49-006e6b499097'	System	01 Sep 2020 17:23:12
User entered 'None (1)'	System	01 Sep 2020 17:23:12

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:23:07', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '7cd43267-556d-44b4-9d49-006e6b499097'	System	01 Sep 2020 17:23:12
User entered '01 Sep 2020 12:23'	System	01 Sep 2020 17:23:12

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 7'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:32:39', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed690021-98a4-410f-a712-26e4d9c2edb1'	System	02 Sep 2020 18:33:16
User entered 'None (1)'	System	02 Sep 2020 18:33:16

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:32:49', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed690021-98a4-410f-a712-26e4d9c2edb1'	System	02 Sep 2020 18:33:16
User entered 'No (N)'	System	02 Sep 2020 18:33:16

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:32:57', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed690021-98a4-410f-a712-26e4d9c2edb1'	System	02 Sep 2020 18:33:16
User entered 'No (N)'	System	02 Sep 2020 18:33:16

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:33:06', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed690021-98a4-410f-a712-26e4d9c2edb1'	System	02 Sep 2020 18:33:16
User entered 'None (1)'	System	02 Sep 2020 18:33:16

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:33:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed690021-98a4-410f-a712-26e4d9c2edb1'	System	02 Sep 2020 18:33:16
User entered '02 Sep 2020 13:33'	System	02 Sep 2020 18:33:16

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:08:35', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45fb347d-fb2b-4fbe-9262-9e57056836ea'	System	27 Aug 2020 22:09:16
User entered 'None (0)'	System	27 Aug 2020 22:09:16

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:08:46', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45fb347d-fb2b-4fbe-9262-9e57056836ea'	System	27 Aug 2020 22:09:16
User entered 'None (0)'	System	27 Aug 2020 22:09:16

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:08:52', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45fb347d-fb2b-4fbe-9262-9e57056836ea'	System	27 Aug 2020 22:09:16
User entered 'None (0)'	System	27 Aug 2020 22:09:16

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:08:55', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45fb347d-fb2b-4fbe-9262-9e57056836ea'	System	27 Aug 2020 22:09:16
User entered 'None (0)'	System	27 Aug 2020 22:09:16

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:08:58', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45fb347d-fb2b-4fbe-9262-9e57056836ea'	System	27 Aug 2020 22:09:16
User entered 'None (0)'	System	27 Aug 2020 22:09:16

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:09:02', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45fb347d-fb2b-4fbe-9262-9e57056836ea'	System	27 Aug 2020 22:09:16
User entered 'None (0)'	System	27 Aug 2020 22:09:16

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:09:06', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45fb347d-fb2b-4fbe-9262-9e57056836ea'	System	27 Aug 2020 22:09:16
User entered 'No (N)'	System	27 Aug 2020 22:09:16

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-27T17:09:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45fb347d-fb2b-4fbe-9262-9e57056836ea'	System	27 Aug 2020 22:09:16
User entered '27 Aug 2020 17:09'	System	27 Aug 2020 22:09:16

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 16:49'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 19:19'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:26:07', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'baced3a8-35f7-4493-bfe1-416793002080'	System	28 Aug 2020 05:26:21
User entered 'None (0)'	System	28 Aug 2020 05:26:21

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:25:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'baced3a8-35f7-4493-bfe1-416793002080'	System	28 Aug 2020 05:26:21
User entered 'None (0)'	System	28 Aug 2020 05:26:21

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:25:17', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'baced3a8-35f7-4493-bfe1-416793002080'	System	28 Aug 2020 05:26:21
User entered 'None (0)'	System	28 Aug 2020 05:26:21

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:25:25', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'baced3a8-35f7-4493-bfe1-416793002080'	System	28 Aug 2020 05:26:21
User entered 'None (0)'	System	28 Aug 2020 05:26:21

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:25:32', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'baced3a8-35f7-4493-bfe1-416793002080'	System	28 Aug 2020 05:26:21
User entered 'None (0)'	System	28 Aug 2020 05:26:21

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:25:36', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'baced3a8-35f7-4493-bfe1-416793002080'	System	28 Aug 2020 05:26:21
User entered 'None (0)'	System	28 Aug 2020 05:26:21

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:25:51', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'baced3a8-35f7-4493-bfe1-416793002080'	System	28 Aug 2020 05:26:21
User entered 'No (N)'	System	28 Aug 2020 05:26:21

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T00:26:17', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'baced3a8-35f7-4493-bfe1-416793002080'	System	28 Aug 2020 05:26:21
User entered '28 Aug 2020 00:26'	System	28 Aug 2020 05:26:21

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '27 Aug 2020 20:14'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 2'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:08:20', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '06b5583f-cc49-4e1f-98f8-3fe3696f1f40'	System	28 Aug 2020 20:09:14
User entered 'None (0)'	System	28 Aug 2020 20:09:14

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:08:35', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '06b5583f-cc49-4e1f-98f8-3fe3696f1f40'	System	28 Aug 2020 20:09:14
User entered 'None (0)'	System	28 Aug 2020 20:09:14

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:08:39', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '06b5583f-cc49-4e1f-98f8-3fe3696f1f40'	System	28 Aug 2020 20:09:14
User entered 'None (0)'	System	28 Aug 2020 20:09:14

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:08:43', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '06b5583f-cc49-4e1f-98f8-3fe3696f1f40'	System	28 Aug 2020 20:09:14
User entered 'None (0)'	System	28 Aug 2020 20:09:14

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:08:49', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '06b5583f-cc49-4e1f-98f8-3fe3696f1f40'	System	28 Aug 2020 20:09:14
User entered 'None (0)'	System	28 Aug 2020 20:09:14

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:08:54', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '06b5583f-cc49-4e1f-98f8-3fe3696f1f40'	System	28 Aug 2020 20:09:14
User entered 'None (0)'	System	28 Aug 2020 20:09:14

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:09:07', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '06b5583f-cc49-4e1f-98f8-3fe3696f1f40'	System	28 Aug 2020 20:09:14
User entered 'No (N)'	System	28 Aug 2020 20:09:14

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-08-28T15:09:11', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '06b5583f-cc49-4e1f-98f8-3fe3696f1f40'	System	28 Aug 2020 20:09:14
User entered '28 Aug 2020 15:09'	System	28 Aug 2020 20:09:14

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 3'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 4'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 5'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 6'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:23:21', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1a041cf8-7b68-460a-b852-2e539083cc1e'	System	01 Sep 2020 17:24:06
User entered 'None (0)'	System	01 Sep 2020 17:24:06

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:23:28', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1a041cf8-7b68-460a-b852-2e539083cc1e'	System	01 Sep 2020 17:24:06
User entered 'None (0)'	System	01 Sep 2020 17:24:06

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:23:33', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1a041cf8-7b68-460a-b852-2e539083cc1e'	System	01 Sep 2020 17:24:06
User entered 'None (0)'	System	01 Sep 2020 17:24:06

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:23:37', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1a041cf8-7b68-460a-b852-2e539083cc1e'	System	01 Sep 2020 17:24:06
User entered 'None (0)'	System	01 Sep 2020 17:24:06

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:23:42', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1a041cf8-7b68-460a-b852-2e539083cc1e'	System	01 Sep 2020 17:24:06
User entered 'None (0)'	System	01 Sep 2020 17:24:06

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:23:48', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1a041cf8-7b68-460a-b852-2e539083cc1e'	System	01 Sep 2020 17:24:06
User entered 'None (0)'	System	01 Sep 2020 17:24:06

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:23:54', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1a041cf8-7b68-460a-b852-2e539083cc1e'	System	01 Sep 2020 17:24:06
User entered 'No (N)'	System	01 Sep 2020 17:24:06

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-01T12:24:03', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1a041cf8-7b68-460a-b852-2e539083cc1e'	System	01 Sep 2020 17:24:06
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 17:24:06

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 7'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:32:15', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '62c14434-2fd3-4144-854b-988d54945adf'	System	02 Sep 2020 18:32:28
User entered 'None (0)'	System	02 Sep 2020 18:32:28

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:31:31', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '62c14434-2fd3-4144-854b-988d54945adf'	System	02 Sep 2020 18:32:28
User entered 'None (0)'	System	02 Sep 2020 18:32:28

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:31:36', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '62c14434-2fd3-4144-854b-988d54945adf'	System	02 Sep 2020 18:32:28
User entered 'None (0)'	System	02 Sep 2020 18:32:28

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:31:40', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '62c14434-2fd3-4144-854b-988d54945adf'	System	02 Sep 2020 18:32:28
User entered 'None (0)'	System	02 Sep 2020 18:32:28

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:31:47', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '62c14434-2fd3-4144-854b-988d54945adf'	System	02 Sep 2020 18:32:28
User entered 'None (0)'	System	02 Sep 2020 18:32:28

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:31:50', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '62c14434-2fd3-4144-854b-988d54945adf'	System	02 Sep 2020 18:32:28
User entered 'None (0)'	System	02 Sep 2020 18:32:28

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:31:58', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '62c14434-2fd3-4144-854b-988d54945adf'	System	02 Sep 2020 18:32:28
User entered 'No (N)'	System	02 Sep 2020 18:32:28

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-02T13:32:24', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '62c14434-2fd3-4144-854b-988d54945adf'	System	02 Sep 2020 18:32:28
User entered '02 Sep 2020 13:32'	System	02 Sep 2020 18:32:28

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:02:48

US3922043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	08 Sep 2020 22:22:40

US3922043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 12:26:41
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'pt answered the phone today and not within the window. ' (Site from System).	Patrick Brooks (b) (4) (b) (4)	08 Sep 2020 22:23:02
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Sep 2020 22:22:40
User entered '8 Sep 2020'	Patrick Brooks (b) (4) (b) (4)	08 Sep 2020 22:22:40

US3922043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Patrick Brooks (b) (4)	08 Sep 2020 22:22:40

US3922043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Patrick Brooks (b) (4)	08 Sep 2020 22:22:40

US3922043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	08 Sep 2020 22:23:10

US3922043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	08 Sep 2020 22:23:10

US3922043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Cristina Puig (b) (4)	10 Sep 2020 21:52:27

US3922043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '10 Sep 2020'	(b) (4) Cristina Puig (b) (4)	10 Sep 2020 21:52:27

US3922043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cristina Puig (b) (4) (b) (4)	10 Sep 2020 21:52:27

US3922043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) Cristina Puig (b) (4)	10 Sep 2020 21:52:27
	(b) (4)	

US3922043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Cristina Puig (b) (4)	10 Sep 2020 21:52:35

US3922043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	10 Sep 2020 21:52:35

US3922043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	17 Sep 2020 21:42:29

US3922043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '17 Sep 2020'	Patrick Brooks (b) (4)	17 Sep 2020 21:42:29

US3922043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Patrick Brooks (b) (4)	17 Sep 2020 21:42:29

US3922043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Patrick Brooks (b) (4)	17 Sep 2020 21:42:29

US3922043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	17 Sep 2020 21:43:08

US3922043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	17 Sep 2020 21:43:08

US3922043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Chana Hines (b) (4)	28 Sep 2020 17:06:02

US3922043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '28 Sep 2020'	(b) (4) Chana Hines (b) (4)	28 Sep 2020 17:06:02

US3922043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Clinic (Clinic)'	Chana Hines (b) (4)	28 Sep 2020 17:06:02

US3922043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'VISIT2'	System	28 Sep 2020 17:06:02

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User accepted default value 'Pre-Dose (PREDOSE)'	lynn yauch (b) (4)	29 Sep 2020 17:34:57
	(b) (4)	

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '28 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '10:11'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '28 Sep 2020 10:11'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Per CDM: Re-Query: Per previous response, please confirm if the out of range value is CS/NCS. If CS then report as AE and update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 05:00:32
Query 'Per CDM: Re-Query: Per previous response, please confirm if the out of range value is CS/NCS. If CS then report as AE and update accordingly. Thank you.' answered with 'NCS per source' (Site from DM).	lynn yauch (b) (4) (b) (4)	01 Oct 2020 18:07:15
User opened query 'Per CDM: Re-Query: Per previous response, please confirm if the out of range value is CS/NCS. If CS then report as AE and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 05:08:11
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 05:06:12
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as is' (Site from System).	lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:35:22
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	29 Sep 2020 17:34:57
User entered '96.6' F	lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (Oral)'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '76'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'bpm'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '15'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'breaths/min'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '124'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'mmHg'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '86'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'mmHg'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User accepted default value 'Post-Dose (POSTDOSE)'	lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '28 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Please confirm post-dose vitals time as the dosing time is noted as 11:49, thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:59:24
Query 'Please confirm post-dose vitals time as the dosing time is noted as 11:49, thank you.' answered with 'time of assessment was recorded incorrectly, subject observation time ended at 12:20, vitals taken at end of observation' (Site from CRA).	lynn yauch (b) (4) (b) (4)	01 Oct 2020 18:09:10
User entered '12:21' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	01 Oct 2020 18:09:04
User opened query 'Please confirm post-dose vitals time as the dosing time is noted as 11:49, thank you.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 16:49:14
User entered '11:21'	lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '28 Sep 2020 12:21'	System	01 Oct 2020 18:09:04
User entered '28 Sep 2020 11:21'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '97.5' F	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (Oral)'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '72'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'bpm'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '14'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'breaths/min'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '131'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'mmHg'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '85'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'mmHg'	System	29 Sep 2020 17:34:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:35:48

US3922043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '28 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:35:48

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Chana Hines (b) (4)	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Chana Hines (b) (4)	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Chana Hines (b) (4)	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '28 Sep 2020'	(b) (4) Chana Hines (b) (4)	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Please confirm dosing time - post dose vitals note 11:21 - which would be prior to this time. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:58:17
Query 'Please confirm dosing time - post dose vitals note 11:21 - which would be prior to this time. Thank you.' answered with 'dosing time is correct as is, vitals have been updated' (Site from CRA).	lynn yauch (b) (4)	01 Oct 2020 18:10:08
User opened query 'Please confirm dosing time - post dose vitals note 11:21 - which would be prior to this time. Thank you.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 16:48:38
User entered '11:49'	Chana Hines (b) (4)	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '28 Sep 2020 11:49'	System	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	28 Sep 2020 17:08:04
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	28 Sep 2020 17:08:04
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Chana Hines (b) (4)	28 Sep 2020 17:08:04
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	28 Sep 2020 17:04:54
User entered 'Left Arm (LEFT ARM)'	System	28 Sep 2020 17:04:54
	Chana Hines (b) (4)	28 Sep 2020 17:04:54
	(b) (4)	

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'ONCE'	System	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:41

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 17:04:54

US3922043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:36:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '28 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:36:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '10:19'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:36:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '28 Sep 2020 10:19'	System	29 Sep 2020 17:36:57

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:21:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '28 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	lynn yauch (b) (4)	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '10:45'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '28 Sep 2020 10:45'	System	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	lynn yauch (b) (4)	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered empty.	System	29 Sep 2020 17:37:14

US3922043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Chana Hines (b) (4)	08 Oct 2020 16:19:32

US3922043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '1'	System	08 Oct 2020 16:19:32

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:23:45', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45824fbe-8390-4d47-b9a8-83f58d700606'	System	28 Sep 2020 17:24:12
User entered 'Yes (Y)'	System	28 Sep 2020 17:24:12

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:23:52', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45824fbe-8390-4d47-b9a8-83f58d700606'	System	28 Sep 2020 17:24:12
User entered '97.5'	System	28 Sep 2020 17:24:12

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:23:58', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45824fbe-8390-4d47-b9a8-83f58d700606'	System	28 Sep 2020 17:24:12
User entered 'No (N)'	System	28 Sep 2020 17:24:12

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:24:07', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '45824fbe-8390-4d47-b9a8-83f58d700606'	System	28 Sep 2020 17:24:12
User entered '28 Sep 2020 12:24'	System	28 Sep 2020 17:24:12

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 12:09'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:22:19', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4af517eb-cbf0-41db-9243-bd475742d19f'	System	29 Sep 2020 02:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 02:22:45

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:22:26', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4af517eb-cbf0-41db-9243-bd475742d19f'	System	29 Sep 2020 02:22:45
User entered '97.9'	System	29 Sep 2020 02:22:45

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:22:33', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4af517eb-cbf0-41db-9243-bd475742d19f'	System	29 Sep 2020 02:22:45
User entered 'No (N)'	System	29 Sep 2020 02:22:45

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:22:42', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4af517eb-cbf0-41db-9243-bd475742d19f'	System	29 Sep 2020 02:22:45
User entered '28 Sep 2020 21:22'	System	29 Sep 2020 02:22:45

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 15:34'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 2'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:38:24', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '89bf1ba4-7feb-4b54-ad41-2e33f5fe315c'	System	30 Sep 2020 03:38:50
User entered 'Yes (Y)'	System	30 Sep 2020 03:38:50

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:38:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '89bf1ba4-7feb-4b54-ad41-2e33f5fe315c'	System	30 Sep 2020 03:38:50
User entered '99.1'	System	30 Sep 2020 03:38:50

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:38:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '89bf1ba4-7feb-4b54-ad41-2e33f5fe315c'	System	30 Sep 2020 03:38:50
User entered 'No (N)'	System	30 Sep 2020 03:38:50

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:38:45', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '89bf1ba4-7feb-4b54-ad41-2e33f5fe315c'	System	30 Sep 2020 03:38:50
User entered '29 Sep 2020 22:38'	System	30 Sep 2020 03:38:50

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 3'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 4'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:06:08', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ecef9344-9409-41f8-9668-108b110f3355'	System	02 Oct 2020 15:06:58
User entered 'Yes (Y)'	System	02 Oct 2020 15:06:58

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:06:39', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ecef9344-9409-41f8-9668-108b110f3355'	System	02 Oct 2020 15:06:58
User entered '95.9'	System	02 Oct 2020 15:06:58

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:06:49', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ecef9344-9409-41f8-9668-108b110f3355'	System	02 Oct 2020 15:06:58
User entered 'No (N)'	System	02 Oct 2020 15:06:58

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:06:54', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ecef9344-9409-41f8-9668-108b110f3355'	System	02 Oct 2020 15:06:58
User entered '02 Oct 2020 10:06'	System	02 Oct 2020 15:06:58

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 5'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:30:45', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'a5223f5e-5d83-461e-9d8a-b35272ca8d66'	System	03 Oct 2020 05:31:22
User entered 'Yes (Y)'	System	03 Oct 2020 05:31:22

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:31:03', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'a5223f5e-5d83-461e-9d8a-b35272ca8d66'	System	03 Oct 2020 05:31:22
User entered '97.1'	System	03 Oct 2020 05:31:22

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:31:13', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'a5223f5e-5d83-461e-9d8a-b35272ca8d66'	System	03 Oct 2020 05:31:22
User entered 'No (N)'	System	03 Oct 2020 05:31:22

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:31:19', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'a5223f5e-5d83-461e-9d8a-b35272ca8d66'	System	03 Oct 2020 05:31:22
User entered '03 Oct 2020 00:31'	System	03 Oct 2020 05:31:22

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 6'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 7'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:24:21', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed70c524-8a28-4462-add8-da62ab6b1866'	System	28 Sep 2020 17:24:50
User entered 'None (1)'	System	28 Sep 2020 17:24:50

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:24:27', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed70c524-8a28-4462-add8-da62ab6b1866'	System	28 Sep 2020 17:24:50
User entered 'No (N)'	System	28 Sep 2020 17:24:50

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:24:30', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed70c524-8a28-4462-add8-da62ab6b1866'	System	28 Sep 2020 17:24:50
User entered 'No (N)'	System	28 Sep 2020 17:24:50

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:24:37', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed70c524-8a28-4462-add8-da62ab6b1866'	System	28 Sep 2020 17:24:50
User entered 'None (1)'	System	28 Sep 2020 17:24:50

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:24:45', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ed70c524-8a28-4462-add8-da62ab6b1866'	System	28 Sep 2020 17:24:50
User entered '28 Sep 2020 12:24'	System	28 Sep 2020 17:24:50

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 12:09'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:24:08', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ad7aa38-33bf-47ff-ae91-eb625ab4c20e'	System	29 Sep 2020 02:26:25
User entered 'None (1)'	System	29 Sep 2020 02:26:25

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:25:14', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ad7aa38-33bf-47ff-ae91-eb625ab4c20e'	System	29 Sep 2020 02:26:25
User entered 'No (N)'	System	29 Sep 2020 02:26:25

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:25:20', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ad7aa38-33bf-47ff-ae91-eb625ab4c20e'	System	29 Sep 2020 02:26:25
User entered 'No (N)'	System	29 Sep 2020 02:26:25

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:26:07', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ad7aa38-33bf-47ff-ae91-eb625ab4c20e'	System	29 Sep 2020 02:26:25
User entered 'None (1)'	System	29 Sep 2020 02:26:25

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:26:21', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ad7aa38-33bf-47ff-ae91-eb625ab4c20e'	System	29 Sep 2020 02:26:25
User entered '28 Sep 2020 21:26'	System	29 Sep 2020 02:26:25

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 15:34'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 2'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:39:13', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'eea89a40-27fc-4658-bd41-bfa1b316a553'	System	30 Sep 2020 03:40:48
User entered 'None (1)'	System	30 Sep 2020 03:40:48

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:39:27', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'eea89a40-27fc-4658-bd41-bfa1b316a553'	System	30 Sep 2020 03:40:48
User entered 'No (N)'	System	30 Sep 2020 03:40:48

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:39:43', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'eea89a40-27fc-4658-bd41-bfa1b316a553'	System	30 Sep 2020 03:40:48
User entered 'No (N)'	System	30 Sep 2020 03:40:48

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:40:05', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'eea89a40-27fc-4658-bd41-bfa1b316a553'	System	30 Sep 2020 03:40:48
User entered 'None (1)'	System	30 Sep 2020 03:40:48

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:40:18', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'eea89a40-27fc-4658-bd41-bfa1b316a553'	System	30 Sep 2020 03:40:48
User entered '29 Sep 2020 22:40'	System	30 Sep 2020 03:40:48

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 3'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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)	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 4'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:55', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '183b4b5e-98ab-490b-be07-ca02f03fddaa'	System	02 Oct 2020 15:08:33
User entered 'None (1)'	System	02 Oct 2020 15:08:33

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:08:05', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '183b4b5e-98ab-490b-be07-ca02f03fddaa'	System	02 Oct 2020 15:08:33
User entered 'No (N)'	System	02 Oct 2020 15:08:33

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:08:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '183b4b5e-98ab-490b-be07-ca02f03fddaa'	System	02 Oct 2020 15:08:33
User entered 'No (N)'	System	02 Oct 2020 15:08:33

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:08:15', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '183b4b5e-98ab-490b-be07-ca02f03fddaa'	System	02 Oct 2020 15:08:33
User entered 'None (1)'	System	02 Oct 2020 15:08:33

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:08:29', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '183b4b5e-98ab-490b-be07-ca02f03fddaa'	System	02 Oct 2020 15:08:33
User entered '02 Oct 2020 10:08'	System	02 Oct 2020 15:08:33

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 5'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:31:29', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '841edb35-d197-4b7a-87ad-552c7480758a'	System	03 Oct 2020 05:32:07
User entered 'None (1)'	System	03 Oct 2020 05:32:07

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:31:34', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '841edb35-d197-4b7a-87ad-552c7480758a'	System	03 Oct 2020 05:32:07
User entered 'No (N)'	System	03 Oct 2020 05:32:07

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:31:37', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '841edb35-d197-4b7a-87ad-552c7480758a'	System	03 Oct 2020 05:32:07
User entered 'No (N)'	System	03 Oct 2020 05:32:07

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:31:55', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '841edb35-d197-4b7a-87ad-552c7480758a'	System	03 Oct 2020 05:32:07
User entered 'None (1)'	System	03 Oct 2020 05:32:07

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:32:04', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '841edb35-d197-4b7a-87ad-552c7480758a'	System	03 Oct 2020 05:32:07
User entered '03 Oct 2020 00:32'	System	03 Oct 2020 05:32:07

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 6'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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)	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 7'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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)	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:24:53', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '39549354-5e51-4c08-85f1-c9de0838e899'	System	28 Sep 2020 17:25:38
User entered 'None (0)'	System	28 Sep 2020 17:25:38

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:24:56', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '39549354-5e51-4c08-85f1-c9de0838e899'	System	28 Sep 2020 17:25:38
User entered 'None (0)'	System	28 Sep 2020 17:25:38

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:25:05', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '39549354-5e51-4c08-85f1-c9de0838e899'	System	28 Sep 2020 17:25:38
User entered 'None (0)'	System	28 Sep 2020 17:25:38

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:25:13', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '39549354-5e51-4c08-85f1-c9de0838e899'	System	28 Sep 2020 17:25:38
User entered 'None (0)'	System	28 Sep 2020 17:25:38

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:25:17', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '39549354-5e51-4c08-85f1-c9de0838e899'	System	28 Sep 2020 17:25:38
User entered 'None (0)'	System	28 Sep 2020 17:25:38

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:25:20', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '39549354-5e51-4c08-85f1-c9de0838e899'	System	28 Sep 2020 17:25:38
User entered 'None (0)'	System	28 Sep 2020 17:25:38

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:25:25', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '39549354-5e51-4c08-85f1-c9de0838e899'	System	28 Sep 2020 17:25:38
User entered 'No (N)'	System	28 Sep 2020 17:25:38

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T12:25:33', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '39549354-5e51-4c08-85f1-c9de0838e899'	System	28 Sep 2020 17:25:38
User entered '28 Sep 2020 12:25'	System	28 Sep 2020 17:25:38

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 12:09'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:23:02', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'cfd0340d-17b8-467b-a78e-942e6ede0e32'	System	29 Sep 2020 02:23:43
User entered 'None (0)'	System	29 Sep 2020 02:23:43

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:23:11', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'cfd0340d-17b8-467b-a78e-942e6ede0e32'	System	29 Sep 2020 02:23:43
User entered 'None (0)'	System	29 Sep 2020 02:23:43

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:23:17', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'cfd0340d-17b8-467b-a78e-942e6ede0e32'	System	29 Sep 2020 02:23:43
User entered 'None (0)'	System	29 Sep 2020 02:23:43

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:23:21', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'cfd0340d-17b8-467b-a78e-942e6ede0e32'	System	29 Sep 2020 02:23:43
User entered 'None (0)'	System	29 Sep 2020 02:23:43

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:23:25', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'cfd0340d-17b8-467b-a78e-942e6ede0e32'	System	29 Sep 2020 02:23:43
User entered 'None (0)'	System	29 Sep 2020 02:23:43

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:23:28', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'cfd0340d-17b8-467b-a78e-942e6ede0e32'	System	29 Sep 2020 02:23:43
User entered 'None (0)'	System	29 Sep 2020 02:23:43

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:23:34', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'cfd0340d-17b8-467b-a78e-942e6ede0e32'	System	29 Sep 2020 02:23:43
User entered 'No (N)'	System	29 Sep 2020 02:23:43

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-28T21:23:41', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'cfd0340d-17b8-467b-a78e-942e6ede0e32'	System	29 Sep 2020 02:23:43
User entered '28 Sep 2020 21:23'	System	29 Sep 2020 02:23:43

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '28 Sep 2020 15:34'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 2'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:40:29', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e0b6c50a-3544-4523-bbbf-be277d3639d0'	System	30 Sep 2020 03:41:22
User entered 'None (0)'	System	30 Sep 2020 03:41:22

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:40:36', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e0b6c50a-3544-4523-bbbf-be277d3639d0'	System	30 Sep 2020 03:41:22
User entered 'None (0)'	System	30 Sep 2020 03:41:22

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:40:40', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e0b6c50a-3544-4523-bbbf-be277d3639d0'	System	30 Sep 2020 03:41:22
User entered 'None (0)'	System	30 Sep 2020 03:41:22

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:40:45', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e0b6c50a-3544-4523-bbbf-be277d3639d0'	System	30 Sep 2020 03:41:22
User entered 'None (0)'	System	30 Sep 2020 03:41:22

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:40:53', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e0b6c50a-3544-4523-bbbf-be277d3639d0'	System	30 Sep 2020 03:41:22
User entered 'None (0)'	System	30 Sep 2020 03:41:22

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:41:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e0b6c50a-3544-4523-bbbf-be277d3639d0'	System	30 Sep 2020 03:41:22
User entered 'None (0)'	System	30 Sep 2020 03:41:22

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:41:15', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e0b6c50a-3544-4523-bbbf-be277d3639d0'	System	30 Sep 2020 03:41:22
User entered 'No (N)'	System	30 Sep 2020 03:41:22

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-09-29T22:41:18', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e0b6c50a-3544-4523-bbbf-be277d3639d0'	System	30 Sep 2020 03:41:22
User entered '29 Sep 2020 22:41'	System	30 Sep 2020 03:41:22

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 3'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 4'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:12', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'b218761e-a215-4877-8bd7-c3e090b9bff8'	System	02 Oct 2020 15:07:47
User entered 'None (0)'	System	02 Oct 2020 15:07:47

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:16', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'b218761e-a215-4877-8bd7-c3e090b9bff8'	System	02 Oct 2020 15:07:47
User entered 'None (0)'	System	02 Oct 2020 15:07:47

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:19', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'b218761e-a215-4877-8bd7-c3e090b9bff8'	System	02 Oct 2020 15:07:47
User entered 'None (0)'	System	02 Oct 2020 15:07:47

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:23', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'b218761e-a215-4877-8bd7-c3e090b9bff8'	System	02 Oct 2020 15:07:47
User entered 'None (0)'	System	02 Oct 2020 15:07:47

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:26', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'b218761e-a215-4877-8bd7-c3e090b9bff8'	System	02 Oct 2020 15:07:47
User entered 'None (0)'	System	02 Oct 2020 15:07:47

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:30', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'b218761e-a215-4877-8bd7-c3e090b9bff8'	System	02 Oct 2020 15:07:47
User entered 'None (0)'	System	02 Oct 2020 15:07:47

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:37', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'b218761e-a215-4877-8bd7-c3e090b9bff8'	System	02 Oct 2020 15:07:47
User entered 'No (N)'	System	02 Oct 2020 15:07:47

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-02T10:07:42', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'b218761e-a215-4877-8bd7-c3e090b9bff8'	System	02 Oct 2020 15:07:47
User entered '02 Oct 2020 10:07'	System	02 Oct 2020 15:07:47

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 5'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:32:22', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e499b095-5f1d-4c16-bc6a-514a1abf5c2a'	System	03 Oct 2020 05:33:20
User entered 'None (0)'	System	03 Oct 2020 05:33:20

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:32:30', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e499b095-5f1d-4c16-bc6a-514a1abf5c2a'	System	03 Oct 2020 05:33:20
User entered 'None (0)'	System	03 Oct 2020 05:33:20

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:32:40', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e499b095-5f1d-4c16-bc6a-514a1abf5c2a'	System	03 Oct 2020 05:33:20
User entered 'None (0)'	System	03 Oct 2020 05:33:20

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:32:45', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e499b095-5f1d-4c16-bc6a-514a1abf5c2a'	System	03 Oct 2020 05:33:20
User entered 'None (0)'	System	03 Oct 2020 05:33:20

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:32:58', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e499b095-5f1d-4c16-bc6a-514a1abf5c2a'	System	03 Oct 2020 05:33:20
User entered 'None (0)'	System	03 Oct 2020 05:33:20

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:33:02', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e499b095-5f1d-4c16-bc6a-514a1abf5c2a'	System	03 Oct 2020 05:33:20
User entered 'None (0)'	System	03 Oct 2020 05:33:20

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:33:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e499b095-5f1d-4c16-bc6a-514a1abf5c2a'	System	03 Oct 2020 05:33:20
User entered 'No (N)'	System	03 Oct 2020 05:33:20

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be9041494f047cec)', Time: '2020-10-03T00:33:15', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'e499b095-5f1d-4c16-bc6a-514a1abf5c2a'	System	03 Oct 2020 05:33:20
User entered '03 Oct 2020 00:33'	System	03 Oct 2020 05:33:20

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 6'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	28 Sep 2020 17:04:54
User entered 'Day 7'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

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) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:07:09

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 17:04:54

US3922043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 17:04:54

US3922043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Chana Hines (b) (4)	08 Oct 2020 16:22:06

US3922043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	08 Oct 2020 16:22:24
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Oct 2020 16:22:24
User entered '6 Oct 2020' reason for change: Data Entry Error	Chana Hines (b) (4)	08 Oct 2020 16:22:24
	(b) (4)	
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 16:22:06
User entered '6 Sep 2020'	Chana Hines (b) (4)	08 Oct 2020 16:22:06
	(b) (4)	

US3922043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chana Hines (b) (4)	08 Oct 2020 16:22:06

US3922043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'SC Lead LC completed safety call day 36 within window.'	(b) (4) Chana Hines (b) (4)	08 Oct 2020 16:22:06

US3922043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Chana Hines (b) (4)	08 Oct 2020 16:22:33

US3922043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	08 Oct 2020 16:22:33

US3922043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	12 Oct 2020 20:50:57

US3922043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '12 Oct 2020'	Pauline Jackson (b) (4)	12 Oct 2020 20:50:57

US3922043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	12 Oct 2020 20:50:57

US3922043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Pauline Jackson (b) (4)	12 Oct 2020 20:50:57

US3922043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	12 Oct 2020 20:51:01

US3922043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	12 Oct 2020 20:51:01

US3922043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	19 Oct 2020 21:25:12

US3922043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '19 Oct 2020'	Pauline Jackson (b) (4)	19 Oct 2020 21:25:12

US3922043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	19 Oct 2020 21:25:12

US3922043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Pauline Jackson (b) (4)	19 Oct 2020 21:25:12

US3922043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	19 Oct 2020 21:25:17

US3922043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	19 Oct 2020 21:25:17

US3922043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:22

US3922043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '23 Oct 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:22

US3922043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Clinic (Clinic)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:22

US3922043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'VISIT3'	System	26 Oct 2020 16:00:22

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered empty.	System	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered empty.	System	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered empty.	System	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered empty.	System	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered empty.	System	26 Oct 2020 16:00:29

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 Apr 2021 19:00:40

US3922043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 Apr 2021 19:00:40

US3922043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:34

US3922043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:34

US3922043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:01:13

US3922043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '23 Oct 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:01:13

US3922043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '11:40'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:01:13

US3922043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered '23 Oct 2020 11:40'	System	26 Oct 2020 16:01:13

US3922043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:00:56

US3922043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	26 Oct 2020 16:00:56

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 64'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-10-29T05:34:39', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ef99a145-6865-4220-ab44-c0a8a565cc2f'	System	29 Oct 2020 10:35:02
User entered 'No (N)'	System	29 Oct 2020 10:35:02

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Have you been exposed to someone with 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 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-10-29T05:34:47', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ef99a145-6865-4220-ab44-c0a8a565cc2f'	System	29 Oct 2020 10:35:02
User entered 'No (N)'	System	29 Oct 2020 10:35:02

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-10-29T05:34:58', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'ef99a145-6865-4220-ab44-c0a8a565cc2f' User entered '29 Oct 2020 05:34:58'	System	29 Oct 2020 10:35:02
	System	29 Oct 2020 10:35:02

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 71'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-11-05T10:47:06', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '924b5e2c-736c-4281-80f4-cf812d0fe8fa'	System	05 Nov 2020 16:47:28
User entered 'No (N)'	System	05 Nov 2020 16:47:28

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-11-05T10:47:14', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '924b5e2c-736c-4281-80f4-cf812d0fe8fa'	System	05 Nov 2020 16:47:28
User entered 'No (N)'	System	05 Nov 2020 16:47:28

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-11-05T10:47:24', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '924b5e2c-736c-4281-80f4-cf812d0fe8fa'	System	05 Nov 2020 16:47:28
User entered '05 Nov 2020 10:47:24'	System	05 Nov 2020 16:47:28

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered 'Day 78'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-11-10T08:15:30', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4860b508-7d6e-4d46-aa82-3f9d9c6550bb'	System	10 Nov 2020 14:15:46
User entered 'No (N)'	System	10 Nov 2020 14:15:46

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-11-10T08:15:35', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4860b508-7d6e-4d46-aa82-3f9d9c6550bb'	System	10 Nov 2020 14:15:46
User entered 'No (N)'	System	10 Nov 2020 14:15:46

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-11-10T08:15:43', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4860b508-7d6e-4d46-aa82-3f9d9c6550bb' User entered '10 Nov 2020 08:15:43'	System	10 Nov 2020 14:15:46
	System	10 Nov 2020 14:15:46

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 22:02:48

US3922043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:07:09
Data entry locked.	System	27 Aug 2020 22:02:48
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 22:02:48

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (2873a877d3826a63)', Time: '2020-11-21T12:48:25', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4eb445e6-6cc7-4109-89a6-a6740547c26f'	System	22 Nov 2020 12:36:46
User entered 'No (N)'	System	22 Nov 2020 12:36:46

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (2873a877d3826a63)', Time: '2020-11-22T06:36:32', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4eb445e6-6cc7-4109-89a6-a6740547c26f'	System	22 Nov 2020 12:36:46
User entered 'No (N)'	System	22 Nov 2020 12:36:46

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-11-22T06:36:42', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4eb445e6-6cc7-4109-89a6-a6740547c26f' User entered '22 Nov 2020 06:36:42'	System	22 Nov 2020 12:36:46
	System	22 Nov 2020 12:36:46

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (2873a877d3826a63)', Time: '2020-11-28T18:22:02', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '900b971e-26d9-4b41-bcc4-3b2f45b677e2'	System	29 Nov 2020 00:22:17
User entered 'No (N)'	System	29 Nov 2020 00:22:17

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (2873a877d3826a63)', Time: '2020-11-28T18:22:08', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '900b971e-26d9-4b41-bcc4-3b2f45b677e2'	System	29 Nov 2020 00:22:17
User entered 'No (N)'	System	29 Nov 2020 00:22:17

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-11-28T18:22:14', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '900b971e-26d9-4b41-bcc4-3b2f45b677e2'	System	29 Nov 2020 00:22:17
User entered '28 Nov 2020 18:22:14'	System	29 Nov 2020 00:22:17

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (2873a877d3826a63)', Time: '2020-12-06T22:05:13', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '9351653e-d2f0-473f-8a49-09b3a1cfc25a'	System	07 Dec 2020 04:06:21
User entered 'No (N)'	System	07 Dec 2020 04:06:21

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (2873a877d3826a63)', Time: '2020-12-06T22:05:23', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '9351653e-d2f0-473f-8a49-09b3a1cfc25a'	System	07 Dec 2020 04:06:21
User entered 'No (N)'	System	07 Dec 2020 04:06:21

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-12-06T22:05:49', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '9351653e-d2f0-473f-8a49-09b3a1cfc25a'	System	07 Dec 2020 04:06:21
User entered '06 Dec 2020 22:05:49'	System	07 Dec 2020 04:06:21

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (2873a877d3826a63)', Time: '2020-12-13T22:25:59', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'aba9accd-1d79-46b8-ae04-31e67236e269'	System	14 Dec 2020 04:26:26
User entered 'No (N)'	System	14 Dec 2020 04:26:26

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (2873a877d3826a63)', Time: '2020-12-13T22:26:16', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'aba9accd-1d79-46b8-ae04-31e67236e269'	System	14 Dec 2020 04:26:26
User entered 'No (N)'	System	14 Dec 2020 04:26:26

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-12-13T22:26:22', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'aba9accd-1d79-46b8-ae04-31e67236e269'	System	14 Dec 2020 04:26:26
User entered '13 Dec 2020 22:26:22'	System	14 Dec 2020 04:26:26

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (2873a877d3826a63)', Time: '2020-12-19T02:10:14', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ef16faf-1028-41d9-8a11-066349514a28'	System	19 Dec 2020 08:10:56
User entered 'No (N)'	System	19 Dec 2020 08:10:56

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (2873a877d3826a63)', Time: '2020-12-19T02:10:47', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ef16faf-1028-41d9-8a11-066349514a28'	System	19 Dec 2020 08:10:56
User entered 'No (N)'	System	19 Dec 2020 08:10:56

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2873a877d3826a63)', Time: '2020-12-19T02:10:53', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ef16faf-1028-41d9-8a11-066349514a28'	System	19 Dec 2020 08:10:56
User entered '19 Dec 2020 02:10:53'	System	19 Dec 2020 08:10:56

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2020-12-29T12:17:57', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'a69f11a6-0b8c-45ff-a660-c17649c31136'	System	29 Dec 2020 18:18:16
User entered 'No (N)'	System	29 Dec 2020 18:18:16

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2020-12-29T12:18:04', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'a69f11a6-0b8c-45ff-a660-c17649c31136'	System	29 Dec 2020 18:18:16
User entered 'No (N)'	System	29 Dec 2020 18:18:16

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2020-12-29T12:18:09', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'a69f11a6-0b8c-45ff-a660-c17649c31136'	System	29 Dec 2020 18:18:16
User entered '29 Dec 2020 12:18:09'	System	29 Dec 2020 18:18:16

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-01-02T01:10:24', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '3c63491d-7268-4f71-bf68-e004da5a140a' User entered 'No (N)'	System	02 Jan 2021 07:10:38

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-01-02T01:10:29', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '3c63491d-7268-4f71-bf68-e004da5a140a'	System	02 Jan 2021 07:10:38
User entered 'No (N)'	System	02 Jan 2021 07:10:38

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-01-02T01:10:35', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '3c63491d-7268-4f71-bf68-e004da5a140a' User entered '02 Jan 2021 01:10:35'	System	02 Jan 2021 07:10:38
	System	02 Jan 2021 07:10:38

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-01-09T00:02:52', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '2a5c421e-be15-4948-b3fc-c2d22921da7b'	System	09 Jan 2021 06:03:40
User entered 'No (N)'	System	09 Jan 2021 06:03:40

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-01-09T00:03:02', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '2a5c421e-be15-4948-b3fc-c2d22921da7b'	System	09 Jan 2021 06:03:40
User entered 'No (N)'	System	09 Jan 2021 06:03:40

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-01-09T00:03:08', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '2a5c421e-be15-4948-b3fc-c2d22921da7b'	System	09 Jan 2021 06:03:40
User entered '09 Jan 2021 00:03:08'	System	09 Jan 2021 06:03:40

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-01-20T09:29:34', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '03344bfc-d6c4-4453-a567-7b6c3dd20162'	System	20 Jan 2021 15:29:46
User entered 'No (N)'	System	20 Jan 2021 15:29:46

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-01-20T09:29:39', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '03344bfc-d6c4-4453-a567-7b6c3dd20162'	System	20 Jan 2021 15:29:46
User entered 'No (N)'	System	20 Jan 2021 15:29:46

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-01-20T09:29:43', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '03344bfc-d6c4-4453-a567-7b6c3dd20162'	System	20 Jan 2021 15:29:46
User entered '20 Jan 2021 09:29:43'	System	20 Jan 2021 15:29:46

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-01-23T23:43:35', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '454fcfb2-f083-4a78-a9db-6b4168b38333'	System	24 Jan 2021 05:43:50
User entered 'No (N)'	System	24 Jan 2021 05:43:50

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-01-23T23:43:40', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '454fcfb2-f083-4a78-a9db-6b4168b38333'	System	24 Jan 2021 05:43:50
User entered 'No (N)'	System	24 Jan 2021 05:43:50

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-01-23T23:43:43', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '454fcfb2-f083-4a78-a9db-6b4168b38333'	System	24 Jan 2021 05:43:50
User entered '23 Jan 2021 23:43:43'	System	24 Jan 2021 05:43:50

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-01-30T12:42:19', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '8e138662-967f-42b4-b386-85206252bd80'	System	30 Jan 2021 18:42:28
User entered 'No (N)'	System	30 Jan 2021 18:42:28

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-01-30T12:42:23', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '8e138662-967f-42b4-b386-85206252bd80'	System	30 Jan 2021 18:42:28
User entered 'No (N)'	System	30 Jan 2021 18:42:28

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-01-30T12:42:26', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '8e138662-967f-42b4-b386-85206252bd80'	System	30 Jan 2021 18:42:28
User entered '30 Jan 2021 12:42:26'	System	30 Jan 2021 18:42:28

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-02-06T21:36:39', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '41dc2f1f-7888-4f5f-b77e-a04b40ae05fe'	System	07 Feb 2021 03:36:49
User entered 'No (N)'	System	07 Feb 2021 03:36:49

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-02-06T21:36:42', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '41dc2f1f-7888-4f5f-b77e-a04b40ae05fe'	System	07 Feb 2021 03:36:49
User entered 'No (N)'	System	07 Feb 2021 03:36:49

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-02-06T21:36:47', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '41dc2f1f-7888-4f5f-b77e-a04b40ae05fe'	System	07 Feb 2021 03:36:49
User entered '06 Feb 2021 21:36:47'	System	07 Feb 2021 03:36:49

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-02-15T02:45:27', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '0e90095f-9bd3-4200-8840-99c18f74acf2'	System	15 Feb 2021 08:45:37
User entered 'No (N)'	System	15 Feb 2021 08:45:37

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-02-15T02:45:30', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '0e90095f-9bd3-4200-8840-99c18f74acf2'	System	15 Feb 2021 08:45:37
User entered 'No (N)'	System	15 Feb 2021 08:45:37

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-02-15T02:45:33', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '0e90095f-9bd3-4200-8840-99c18f74acf2'	System	15 Feb 2021 08:45:37
User entered '15 Feb 2021 02:45:33'	System	15 Feb 2021 08:45:37

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-02-20T12:25:27', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'aec795ad-347b-4feb-afe7-118cf4f8f924'	System	20 Feb 2021 18:25:53
User entered 'No (N)'	System	20 Feb 2021 18:25:53

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-02-20T12:25:33', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'aec795ad-347b-4feb-afe7-118cf4f8f924'	System	20 Feb 2021 18:25:53
User entered 'No (N)'	System	20 Feb 2021 18:25:53

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-02-20T12:25:49', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'aec795ad-347b-4feb-afe7-118cf4f8f924'	System	20 Feb 2021 18:25:53
User entered '20 Feb 2021 12:25:49'	System	20 Feb 2021 18:25:53

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-03-15T12:30:51-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4cd2238a-298b-479e-9f34-a48004959c4c'	System	15 Mar 2021 17:31:29
User entered 'No (N)'	System	15 Mar 2021 17:31:29

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-03-15T12:30:57-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4cd2238a-298b-479e-9f34-a48004959c4c'	System	15 Mar 2021 17:31:29
User entered 'No (N)'	System	15 Mar 2021 17:31:29

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-03-15T12:31:01-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '4cd2238a-298b-479e-9f34-a48004959c4c' User entered '15 Mar 2021 12:31:01'	System	15 Mar 2021 17:31:29

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-03-21T07:04:47-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1e8d8982-eb0f-47ee-b614-7a7a21768d49'	System	21 Mar 2021 12:05:08
User entered 'No (N)'	System	21 Mar 2021 12:05:08

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-03-21T07:04:55-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1e8d8982-eb0f-47ee-b614-7a7a21768d49'	System	21 Mar 2021 12:05:08
User entered 'No (N)'	System	21 Mar 2021 12:05:08

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-03-21T07:05:04-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '1e8d8982-eb0f-47ee-b614-7a7a21768d49' User entered '21 Mar 2021 07:05:04'	System	21 Mar 2021 12:05:08
	System	21 Mar 2021 12:05:08

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-03-27T11:22:04-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'bc1d4efd-f393-4a49-8ceb-804d51a7fdb4'	System	27 Mar 2021 16:22:17
User entered 'No (N)'	System	27 Mar 2021 16:22:17

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-03-27T11:22:08-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'bc1d4efd-f393-4a49-8ceb-804d51a7fdb4'	System	27 Mar 2021 16:22:17
User entered 'No (N)'	System	27 Mar 2021 16:22:17

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-03-27T11:22:11-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'bc1d4efd-f393-4a49-8ceb-804d51a7fdb4'	System	27 Mar 2021 16:22:17
User entered '27 Mar 2021 11:22:11'	System	27 Mar 2021 16:22:17

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-04-03T05:58:12-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '7241bf62-7f06-41a8-8534-a22ad23929e5' User entered 'No (N)'	System	03 Apr 2021 10:58:28
	System	03 Apr 2021 10:58:28

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-04-03T05:58:21-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '7241bf62-7f06-41a8-8534-a22ad23929e5'	System	03 Apr 2021 10:58:28
User entered 'No (N)'	System	03 Apr 2021 10:58:28

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-04-03T05:58:24-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '7241bf62-7f06-41a8-8534-a22ad23929e5'	System	03 Apr 2021 10:58:28
User entered '03 Apr 2021 05:58:24'	System	03 Apr 2021 10:58:28

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-04-11T22:29:55-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '98a0d43b-e558-4f01-8a7c-5609d983a590'	System	12 Apr 2021 03:31:14
User entered 'Yes (Y)'	System	12 Apr 2021 03:31:14

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-04-11T22:30:14-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '98a0d43b-e558-4f01-8a7c-5609d983a590'	System	12 Apr 2021 03:31:14
User entered 'No (N)'	System	12 Apr 2021 03:31:14

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-04-11T22:30:28-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '98a0d43b-e558-4f01-8a7c-5609d983a590'	System	12 Apr 2021 03:31:14
User entered 'No (N)'	System	12 Apr 2021 03:31:14

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-04-11T22:31:01-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '98a0d43b-e558-4f01-8a7c-5609d983a590'	System	12 Apr 2021 03:31:14
User entered 'No (N)'	System	12 Apr 2021 03:31:14

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-04-11T22:31:10-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '98a0d43b-e558-4f01-8a7c-5609d983a590'	System	12 Apr 2021 03:31:14
User entered '11 Apr 2021 22:31:10'	System	12 Apr 2021 03:31:14

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-04-17T19:32:19-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'fb4b452d-8ea0-4af1-af9d-dd38174d5048'	System	18 Apr 2021 00:33:09
User entered 'Yes (Y)'	System	18 Apr 2021 00:33:09

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-04-17T19:32:29-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'fb4b452d-8ea0-4af1-af9d-dd38174d5048'	System	18 Apr 2021 00:33:09
User entered 'No (N)'	System	18 Apr 2021 00:33:09

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-04-17T19:32:36-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'fb4b452d-8ea0-4af1-af9d-dd38174d5048'	System	18 Apr 2021 00:33:09
User entered 'No (N)'	System	18 Apr 2021 00:33:09

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-04-17T19:33:01-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'fb4b452d-8ea0-4af1-af9d-dd38174d5048'	System	18 Apr 2021 00:33:09
User entered 'No (N)'	System	18 Apr 2021 00:33:09

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-04-17T19:33:05-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'fb4b452d-8ea0-4af1-af9d-dd38174d5048'	System	18 Apr 2021 00:33:09
User entered '17 Apr 2021 19:33:05'	System	18 Apr 2021 00:33:09

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[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 (3e01d861791ec289)', Time: '2021-04-24T06:53:49-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ba7677c-3d1b-4c6d-ae50-320e1caa9dd9' User entered 'No (N)'	System	24 Apr 2021 11:54:05
	System	24 Apr 2021 11:54:05

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

Have you been exposed to someone with 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 (3e01d861791ec289)', Time: '2021-04-24T06:53:58-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ba7677c-3d1b-4c6d-ae50-320e1caa9dd9' User entered 'No (N)'	System	24 Apr 2021 11:54:05
	System	24 Apr 2021 11:54:05

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-04-24T06:54:00-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: '5ba7677c-3d1b-4c6d-ae50-320e1caa9dd9' User entered '24 Apr 2021 06:54:00'	System	24 Apr 2021 11:54:05
	System	24 Apr 2021 11:54:05

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:11:39

US3922043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:39
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:11:39

US3922043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:21:41

[Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:23:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-03-15T12:32:28-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'bdc03c0e-555f-4663-86b9-56456bc22a91'	System	15 Mar 2021 17:32:39
User entered 'No (N)'	System	15 Mar 2021 17:32:39

US3922043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:21:41

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:23:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e01d861791ec289)', Time: '2021-03-15T12:32:32-05:00', User OID: 'PatientReportedOutcome (US3922043)', ODM File OID: 'bdc03c0e-555f-4663-86b9-56456bc22a91'	System	15 Mar 2021 17:32:39
User entered '15 Mar 2021 12:32:32'	System	15 Mar 2021 17:32:39

US3922043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Chana Hines (b) (4)	25 Nov 2020 22:40:54

US3922043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '25 Nov 2020'	Chana Hines (b) (4)	25 Nov 2020 22:40:54

US3922043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chana Hines (b) (4)	25 Nov 2020 22:40:54

US3922043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Chana Hines (b) (4)	25 Nov 2020 22:40:54

US3922043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Chana Hines (b) (4)	25 Nov 2020 22:41:00

US3922043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:00:40
User entered 'I'	System	25 Nov 2020 22:41:00

US3922043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	30 Dec 2020 19:40:41

US3922043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '30 Dec 2020'	Jennifer Ruiz (b) (4)	30 Dec 2020 19:40:41

US3922043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	Jennifer Ruiz (b) (4)	30 Dec 2020 19:40:41

US3922043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Jennifer Ruiz (b) (4)	30 Dec 2020 19:40:41

US3922043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	30 Dec 2020 19:40:45

US3922043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered 'I'	System	30 Dec 2020 19:40:45

US3922043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Pamela Echols (b) (4)	28 Jan 2021 19:54:50

US3922043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '25 Jan 2021'	Pamela Echols (b) (4)	28 Jan 2021 19:54:50

US3922043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Contact Made (CONTACT MADE)'	Pamela Echols (b) (4)	28 Jan 2021 19:54:50

US3922043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	Pamela Echols (b) (4)	28 Jan 2021 19:54:50

US3922043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	Pamela Echols (b) (4)	28 Jan 2021 19:55:00

US3922043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered 'I'	System	28 Jan 2021 19:55:00

US3922043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	25 Feb 2021 19:23:32
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	25 Feb 2021 00:36:09

US3922043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	25 Feb 2021 19:23:32
User entered '24 Feb 2021'	Jennifer Ruiz (b) (4)	25 Feb 2021 00:36:09

US3922043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	25 Feb 2021 19:23:32
User entered 'Contact Made (CONTACT MADE)'	Jennifer Ruiz (b) (4)	25 Feb 2021 00:36:09

US3922043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	25 Feb 2021 19:23:32
User entered empty.	Jennifer Ruiz (b) (4)	25 Feb 2021 00:36:09

US3922043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	25 Feb 2021 19:23:32
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	25 Feb 2021 00:36:14

US3922043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered 'I'	System	25 Feb 2021 00:36:14

US3922043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Mar 2021 18:44:47

US3922043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User entered '15 Mar 2021'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Mar 2021 18:44:47

US3922043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User entered 'Clinic (Clinic)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Mar 2021 18:44:47

US3922043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered 'VISIT4'	System	16 Mar 2021 18:44:47

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered 'No (N)'	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered empty.	System	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered empty.	System	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered empty.	System	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered empty.	System	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:03
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered empty.	System	30 Mar 2021 18:06:20

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	14 Apr 2021 07:32:32

US3922043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32

US3922043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	16 Mar 2021 18:45:56
User entered 'No (N)'	System	16 Mar 2021 18:45:40
	lynn yauch (b) (4)	16 Mar 2021 18:45:40
	(b) (4)	

US3922043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	16 Mar 2021 18:45:56
User entered '15 Mar 2021'	lynn yauch (b) (4)	16 Mar 2021 18:45:40

US3922043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Mar 2021 18:47:15

US3922043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User entered '15 Mar 2021'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Mar 2021 18:47:15

US3922043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User entered '12:15'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Mar 2021 18:47:15

US3922043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered '15 Mar 2021 12:15'	System	16 Mar 2021 18:47:15

US3922043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:12
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Mar 2021 18:45:17

US3922043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:32:32
User entered '1'	System	16 Mar 2021 18:45:17

US3922043

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

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	08 Feb 2021 18:19:17
	(b) (4)	

US3922043

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

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:19:17
	(b) (4)	

US3922043

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

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Clinic (Clinic)'	Pamela Echols (b) (4)	08 Feb 2021 18:19:17
	(b) (4)	

US3922043

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

Form: Visit Date

Generated On: 10 Jun 2021 10:21:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 18:19:17

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43
	(b) (4)	

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 21:01:44
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:46:48

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43
	(b) (4)	

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 21:01:44
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:46:48

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43
	(b) (4)	

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43
	(b) (4)	

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43
	(b) (4)	

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43
	(b) (4)	

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43
	(b) (4)	

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	08 Feb 2021 18:20:43

US3922043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered empty.	System	08 Feb 2021 18:20:43

US3922043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	08 Feb 2021 18:21:25
	(b) (4)	

US3922043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:21:25
	(b) (4)	

US3922043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '10:49'	Pamela Echols (b) (4)	08 Feb 2021 18:21:25
	(b) (4)	

US3922043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '05 Feb 2021 10:49'	System	08 Feb 2021 18:21:25

US3922043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:21:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	08 Feb 2021 18:21:56
	(b) (4)	

US3922043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:21:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:21:56
	(b) (4)	

US3922043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:21:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '10:57'	Pamela Echols (b) (4)	08 Feb 2021 18:21:56
	(b) (4)	

US3922043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:21:41

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:08:01
User entered '05 Feb 2021 10:57'	System	08 Feb 2021 18:21:56

US3922043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:21:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:28:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:29
Signature has been broken.	(b) (4)	
	Ladina Garcia (b) (4)	22 Apr 2021 21:39:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Ladina Garcia (b) (4)	22 Apr 2021 21:39:06
User signature succeeded.	(b) (4)	
	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4)	
	Cristina Puig (b) (4)	04 Sep 2020 15:03:23
	(b) (4)	

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 14:41:57
User entered 'USA-US212-2021-mRNA-1273-P301000010'	System	23 Apr 2021 14:36:33
User entered 'New'	(b) (4), (b) (6)	23 Apr 2021 14:36:33

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[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)	30 Apr 2021 21:50:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 21:53:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 21:53:08
Data point term sent to Coder	System	22 Apr 2021 21:52:03
User entered 'Shortness of breath'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User entered '09 Apr 2021'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). User entered empty.	(b) (4), (b) (6) Ladina Garcia (b) (4) (b) (4)	30 Apr 2021 21:49:50 22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Apr 2021'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Apr 2021'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	22 Apr 2021 21:51:56
User entered 'Unknown (UNK)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Apr 2021 21:58:35
User entered '1' reason for change: Data Entry Error	Ladina Garcia (b) (4)	22 Apr 2021 21:58:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	22 Apr 2021 21:51:56
User entered '0'	System	22 Apr 2021 21:51:56
	Ladina Garcia (b) (4)	22 Apr 2021 21:51:56
	(b) (4)	

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Outcome](#)

Audit	User	Time (GMT)
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)	30 Apr 2021 21:50:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:50:40
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)	30 Apr 2021 21:50:19
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)	30 Apr 2021 21:49:32
User entered empty.	Ladina Garcia (b) (4) (b) (4)	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:51:56

US3922043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 21:51:56

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:21:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:28:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Sep 2020 21:01:34

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Sep 2020 14:56:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:56:45
Data point term sent to Coder	System	15 Sep 2020 14:55:34
User entered 'amlodipine'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	15 Sep 2020 14:55:28
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'hypertension'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '10'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:55:28
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2013'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 14:55:28

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:43:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:43:09
Data point term sent to Coder	System	22 Feb 2021 20:27:34
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:57:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:57:49
Data point term sent to Coder	System	15 Sep 2020 14:56:35
User entered 'atorvastatin'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'hypercholesterolemia'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '20'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:56:13
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 14:56:13

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:11
Data point term sent to Coder	System	22 Feb 2021 20:27:34
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:05:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:05:09
Data point term sent to Coder	System	17 Nov 2020 20:27:05
Coding entries removed.	Lorine Cook (b) (4) (b) (4)	17 Nov 2020 20:26:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:07:29
Data point term sent to Coder	System	26 Oct 2020 15:59:21
Coding entries removed.	lynn yauch (b) (4) (b) (4)	26 Oct 2020 15:58:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:59:04

PRODUCTION RELEASE (v12.003
EAB) (1725)

1727 of 1953

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:59:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:58:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:58:52
Data point term sent to Coder	System	15 Sep 2020 14:57:36
User entered 'gabapentin'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	15 Sep 2020 14:56:52
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Per CDM: Please consider adding the term "Sensory" to this field, in accordance with updated MH term "NEUROPATHY DIABETIC BILATERAL FEET (SENSORY)" in MH eCRF, to ensure consistency of data between ConMed eCRF and MH eCRF. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:58:15
Query 'Per CDM: Please consider adding the term "Sensory" to this field, in accordance with updated MH term "NEUROPATHY DIABETIC BILATERAL FEET (SENSORY)" in MH eCRF, to ensure consistency of data between ConMed eCRF and MH eCRF. Thank you.' answered with 'Updated' (Site from DM).	Lorine Cook (b) (4) (b) (4)	17 Nov 2020 20:26:42
User entered 'Sensory NEUROPATHY DIABETIC BILATERAL FEET' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	17 Nov 2020 20:26:23
User opened query 'Per CDM: Please consider adding the term "Sensory" to this field, in accordance with updated MH term "NEUROPATHY DIABETIC BILATERAL FEET (SENSORY)" in MH eCRF, to ensure consistency of data between ConMed eCRF and MH eCRF. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 12:16:06
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 18:29:13
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match' answered with 'updated due to updated MH' (Site from DM).	lynn yauch (b) (4) (b) (4)	26 Oct 2020 15:59:24
User entered 'NEUROPATHY diabetic bilateral feet' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	26 Oct 2020 15:58:58

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match ' (Site from DM). User entered 'neuropathy'	(b) (4), (b) (6) (b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 05:25:00 15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '300'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:56:52
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:56:52
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:56:52
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:56:52
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 14:56:52

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:05
Data point term sent to Coder	System	22 Feb 2021 20:27:32
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 12:05:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 12:05:59
Data point term sent to Coder	System	15 Sep 2020 14:57:36
User entered 'jardaiance'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'type2 diabetes'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '25'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:57:29
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:57:29
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	15 Sep 2020 14:57:29
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 14:57:29

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:07
Data point term sent to Coder	System	22 Feb 2021 20:27:32
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:59:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:59:50
Data point term sent to Coder	System	15 Sep 2020 14:58:37
User entered 'lisinopril'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'hypertension'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '40'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:58:11
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:58:11
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:58:11
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 14:58:11

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:08
Data point term sent to Coder	System	22 Feb 2021 20:27:35
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 15:00:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 15:00:42
Data point term sent to Coder	System	15 Sep 2020 14:59:40
User entered 'metoprolol'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'hypertension'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '25'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 14:58:44

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:10
Data point term sent to Coder	System	22 Feb 2021 20:27:35
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:01:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:01:57
Data point term sent to Coder	System	15 Sep 2020 15:00:41
User entered 'pioglitazone'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	15 Sep 2020 14:59:42
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'type2 diabestes'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '30'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:59:42
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:59:42
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 14:59:42
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	15 Sep 2020 14:59:42
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 14:59:42

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: LINAGLIPTIN, PRODUCTSYNONYM: TRAJENTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 20:28:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 20:28:06
Data point term sent to Coder	System	22 Feb 2021 20:27:35
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: LINAGLIPTIN, PRODUCTSYNONYM: TRAJENTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 15:01:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 15:01:51
Data point term sent to Coder	System	15 Sep 2020 15:00:41
User entered 'trajenta'	lynn yauch (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'type2 diabetes'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '5'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 15:00:14
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 15:00:14

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:43:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:43:09
Data point term sent to Coder	System	22 Feb 2021 20:27:34
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:08:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:08:42
Data point term sent to Coder	System	15 Sep 2020 15:06:04
User entered 'triamterene hydrochlorothiazide 37.5/25'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	15 Sep 2020 15:05:02
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'hypertension'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'tablet (TABLET)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 15:05:02
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 15:05:02
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Sep 2020 15:05:02
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 15:05:02

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN ASPART;INSULIN ASPART PROTAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:03
Data point term sent to Coder	System	22 Feb 2021 20:27:35
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN ASPART;INSULIN ASPART PROTAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:06:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:06:36
Data point term sent to Coder	System	15 Sep 2020 15:08:10
User entered 'Insulin aspart protamine/insulin aspart'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'type2 diabetes'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 08:56:44
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Verified with patient on 12/16/2020. Patient also reported ending this CM on 12/15/2020 and starting CM 14.' (Site from DM).	Chana Hines (b) (4) (b) (4)	16 Dec 2020 21:09:19
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 19:46:45
User entered '10/60'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'TU (IU)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	01 Oct 2020 18:00:17
	(b) (4)	
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Sep 2020 15:07:37
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 10:37:05
Query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	01 Oct 2020 18:03:21
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	01 Oct 2020 18:00:17
User opened query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:31:02
User entered 'units'	lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'twice daily (BID)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'un UNK 2017'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 15:07:37

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
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) (b) (4)	22 Feb 2021 20:28:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:04
Data point term sent to Coder	System	22 Feb 2021 20:27:35
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
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) (b) (4)	26 Oct 2020 16:25:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:25:43
Data point term sent to Coder	System	26 Oct 2020 16:04:32
User entered 'flu shot'	lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'flu prophylaxis'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0.5'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'mL (mL)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'once (ONCE)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '11 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '11 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User entered empty.	System	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User entered empty.	System	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:20
User entered empty.	System	26 Oct 2020 16:04:01

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:11
Data point term sent to Coder	System	22 Feb 2021 20:27:35
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:19:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:19:46
Data point term sent to Coder	System	16 Dec 2020 21:15:19
Data point term sent to Coder	System	16 Dec 2020 21:13:17
User entered 'Humalog 72-25 Kwik Pen'	Chana Hines (b) (4) (b) (4)	16 Dec 2020 21:12:32

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'TYPE II - Diabetes Mellitus' reason for change: Data Entry Error	Chana Hines (b) (4)	16 Dec 2020 21:14:26
	(b) (4)	
User entered 'Diabetes Mellitus Type II'	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '35-25'	(b) (4)	
	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'IU (IU)' reason for change: Data Entry	Chana Hines (b) (4)	16 Dec 2020 21:14:26
Error	(b) (4)	
User entered 'Other (OTHER)'	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty; reason for change Data Entry	Chana Hines (b) (4)	16 Dec 2020 21:14:26
Error	(b) (4)	
User entered 'units'	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'twice daily (BID)'	(b) (4) Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Chana Hines (b) (4) (b) (4)	16 Dec 2020 21:12:32

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered empty.	(b) (4)	
	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '15 Dec 2020'	(b) (4)	
	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '0'	(b) (4) Chana Hines (b) (4) (b) (4)	16 Dec 2020 21:12:32

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'No (N)'	(b) (4) Chana Hines (b) (4)	16 Dec 2020 21:12:32
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Dec 2020 21:12:32

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 21:12:32

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Dec 2020 21:12:32

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:04
Data point term sent to Coder	System	22 Feb 2021 20:27:36
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:31
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 17:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 17:51:44
Data point term sent to Coder	System	16 Dec 2020 21:26:28
User entered 'CLOBETASOL PropIONATE Gel .05%' reason for change: Data Entry Error	Chana Hines (b) (4) (b) (4)	16 Dec 2020 21:25:30
Data point term sent to Coder	System	16 Dec 2020 21:23:24
User entered 'Clobetasol pionate ointment 5%'	Chana Hines (b) (4) (b) (4)	16 Dec 2020 21:22:39

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Psoriasis'	(b) (4)	
	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Per DM CLR: Please review and remove the extraneous information (i.e. APPLICATION) from the DOSE field as only the Dose should be recorded in this field. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 10:03:32
Query 'Per DM CLR: Please review and remove the extraneous information (i.e. APPLICATION) from the DOSE field as only the Dose should be recorded in this field. Update eCRF as appropriate.' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	26 Jan 2021 20:49:28
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	26 Jan 2021 20:49:10
User opened query 'Per DM CLR: Please review and remove the extraneous information (i.e. APPLICATION) from the DOSE field as only the Dose should be recorded in this field. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:51:32
User entered '1 application'	Chana Hines (b) (4) (b) (4)	16 Dec 2020 21:22:39

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 21:25:30
User entered 'Other (OTHER)' reason for change: Data Entry Error	System	16 Dec 2020 21:25:30
User opened query 'Data is required. Please complete.' (Site from System).	Chana Hines (b) (4)	16 Dec 2020 21:25:30
User entered empty.	(b) (4)	
	System	16 Dec 2020 21:22:39
	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User closed query 'Per DM CLR: If dose unit is Other, specify = 1 APPLICATION TO AFFECTED AREA (FEET). However, kindly remove the extraneous information as the Unit (Application) should be the only detail recorded in this field. Update eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: If dose unit is Other, specify = 1 APPLICATION TO AFFECTED AREA (FEET). However, kindly remove the extraneous information as the Unit (Application) should be the only detail recorded in this field. Update eCRF as appropriate.'	(b) (4), (b) (6)	29 Jan 2021 10:03:33
answered with 'updated per query' (Site from DM).		
User entered 'application' reason for change: Data Entry Error	lynn yauch (b) (4)	26 Jan 2021 20:49:34
User opened query 'Per DM CLR: If dose unit is Other, specify = 1 APPLICATION TO AFFECTED AREA (FEET). However, kindly remove the extraneous information as the Unit (Application) should be the only detail recorded in this field. Update eCRF as appropriate.'	(b) (4)	
User entered '1 application to affected area (feet)'	(b) (4), (b) (6)	26 Jan 2021 20:49:10
		19 Jan 2021 09:52:16
	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'twice daily (BID)'	(b) (4) Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Topical (TOPICAL)'	(b) (4) Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '25 Nov 2020'	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered '0'	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered 'Yes (Y)'	(b) (4) Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Chana Hines (b) (4)	16 Dec 2020 21:22:39
	(b) (4)	

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Dec 2020 21:22:39

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 21:22:39

US3922043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:21:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Dec 2020 21:22:39

US3922043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:21:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
	(b) (4)	
User entered 'No (N)'	Lorine Cook (b) (4)	04 Sep 2020 20:04:48
	(b) (4)	

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'USA-US212-2021-MRNA-1273-P301000010'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'Yes (Y)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'Yes (Y)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'Jennifer'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'Bashour'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
User entered 'US'	(b) (4) System	23 Apr 2021 14:42:19

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 14:42:19

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'USA-US212-2021-MRNA-1273-P301000010'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'Yes (Y)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'Yes (Y)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'No (N)'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'Jennifer'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:11
User entered 'Bashour'	System	23 Apr 2021 14:36:33

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
User entered 'US'	(b) (4) System	23 Apr 2021 14:42:19

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 14:42:19

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:21:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
User entered '23/Apr/2021 10:42'	(b) (4) System	23 Apr 2021 14:42:19

US3922043

Folder: SAE USA-US212-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:21:41

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.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:19