

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

Generated By: KC Joubran

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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 (*dd MMM yyyy*) 27 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1
Amendment 2
Amendment 3
Amendment 4
Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail Withdrew Consent
Inclusion/Exclusion
Cohort Full
Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

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
No

Visit date (dd MMM yyyy) 27 AUG 2020

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

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 (<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
Temperature (<i>xxx.x</i>)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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 (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:00 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:00
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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.**

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 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.**

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

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.**

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

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.**

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

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.**

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

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.**

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

02 SEP 2020 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

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

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

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

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

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

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
No

Visit date (dd MMM yyyy) 28 SEP 2020

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

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 (<i>dd MMM yyyy</i>)	28 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:11 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:11
Temperature (<i>xxx.x</i>)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:21 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:21
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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 (<i>dd MMM yyyy</i>)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	95.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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.**

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

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.**

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

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.**

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	02 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.**

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	03 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.**

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

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.**

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

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

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

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

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

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
No

Visit date (dd MMM yyyy) 23 OCT 2020

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

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 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 <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	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

Yes

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

No

Yes

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

Date and time of submission 02 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 <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	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

Yes

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

No

Yes

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

Date and time of submission

20 JAN 2021 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 <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	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 <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 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°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

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
Yes

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

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

Yes

Have you been exposed to someone with known SARS-CoV-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 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 <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	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 Yes

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

Have 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):

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

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 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 Yes

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

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°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

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 Yes

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

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 Yes

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

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°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

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
Yes

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

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

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

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

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°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

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 Yes

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

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°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

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°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

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 Yes

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

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 Yes

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

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°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

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 Yes

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

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°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

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
Yes

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

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 Yes

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

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°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

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
Yes

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

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 Yes

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

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
Yes

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

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
Yes

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

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 Yes

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

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 Yes

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

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 Yes

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

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
Yes

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

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°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

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 Yes

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

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 Yes

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

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°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

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
Yes

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

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 Yes

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

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
Yes

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

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
Yes

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

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°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

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°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

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

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
Yes

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

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

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

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°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

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°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

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

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°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

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°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

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°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

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°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

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 Yes

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

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 Yes

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

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
Yes

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

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
Yes

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

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 Yes

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

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 Yes

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

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 Yes

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

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
Yes

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

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°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

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

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
Yes

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

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°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

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
Yes

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

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 Yes

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

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 Yes

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

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
Yes

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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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
Yes

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

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
Yes

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

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 Yes

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

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 Yes

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

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 Yes

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

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 Yes

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

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

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°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

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
Yes

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

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°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

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°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

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
Yes

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

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 Yes

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

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 (<i>dd MMM yyyy</i>)	15 MAR 2021
Collection time (<i>00:00-23:59</i>)	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
No

Visit date (dd MMM yyyy) 05 FEB 2021

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

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 No

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
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 09 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 09 APR 2021

Hospital Discharge Date (dd MMM yyyy) 14 APR 2021

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003 329 of 1953
EAB) (1725)

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
EAB) (1725)

332 of 1953

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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
EAB) (1725)

334 of 1953

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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
EAB) (1725)

342 of 1953

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
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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
No

Indication FLU PROPHYLAXIS
Dose per administration 0.5
Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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
No

If not Ongoing, End date (*dd MMM yyyy*) 11 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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="checkbox"/>
	803 <input type="checkbox"/>
	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-P30 1000010
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
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:14

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
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:10:18

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
User entered 'Clinic (Clinic)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:14

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
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:10:19

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
User entered '60'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered 'Female (F)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '1'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered empty.	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '0'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:34

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
User entered '27 Aug 2020'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49

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
User entered 'Amendment 2 (2)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49

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
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49

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
User entered empty.	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49

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
User entered empty.	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49

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
User entered 'No (N)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:49

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
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:10:18

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
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	27 Aug 2020 22:00:56

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:53:37

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) (b) (4)	22 Feb 2021 20:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 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) (b) (4)	22 Feb 2021 20:27:31
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) (b) (4)	02 Sep 2020 23:54:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (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) (b) (4)	02 Sep 2020 23:54:14

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
User entered 'un UNK 2013'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14

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
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:54:14

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:54:14

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
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
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
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

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
User entered 'un UNK 2003'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25

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
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:54:25

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:54:25

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, HLG: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:28:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (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) (b) (4)	22 Feb 2021 20:27:31
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:55:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (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) (b) (4)	02 Sep 2020 23:55:02

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
User entered 'un UNK 2013'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02

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
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:55:02

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:02

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) (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.	Coder Import (b) (4) (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) (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) (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.	Coder Import (b) (4) (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. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 12:10:04
Data point term sent to Coder	System	02 Nov 2020 20:16:19
User entered 'NEUROPATHY DIABETIC BILATERAL FEET (sensory)' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	02 Nov 2020 20:15:37
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. ' answered with 'subject contacted. explained neuropathy is sensory' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	02 Nov 2020 20:15:29

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) [REDACTED] [REDACTED]	29 Oct 2020 16:05:34
	System	26 Oct 2020 15:59:19
	lynn yauch (b) (4) (b) (4)	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, HLT: 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.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:55:48
Data point term sent to Coder	System	02 Sep 2020 23:55:21
User entered 'neuropathy'	Cristina Puig (b) (4) (b) (4)	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
User entered 'un UNK 2014'	Cristina Puig (b) (4)	02 Sep 2020 23:55:16

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:16

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:55:16

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
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:55:16

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:16

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) (b) (4)	22 Feb 2021 20:28:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (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) (b) (4)	22 Feb 2021 20:27:31
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:56:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (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) (b) (4)	02 Sep 2020 23:55:29

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
User entered 'un UNK 2000'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29

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
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:55:29

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:55:29

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.	Coder Import (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
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.	Coder Import (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

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
User entered 'un UNK 2015'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19

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
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:56:19

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:56:19

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) (b) (4)	22 Feb 2021 20:28:09
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 20:28:09
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 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) (b) (4)	19 Oct 2020 21:26:59
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) (b) (4)	29 Sep 2020 09:25:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (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) (b) (4)	02 Sep 2020 23:57:41

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
User entered 'un UNK 2013'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41

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
User entered 'No (N)'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41

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
User entered 'un UNK 2013'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41

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
User entered '0'	Cristina Puig (b) (4)	02 Sep 2020 23:57:41

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, HLGHT: 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, HLGHT: 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
User entered 'un UNK 1999'	lynn yauch (b) (4)	30 Sep 2020 14:20:04

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
User entered '0'	lynn yauch (b) (4)	30 Sep 2020 14:20:04

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
User entered 'Yes (Y)'	lynn yauch (b) (4)	30 Sep 2020 14:20:04

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
User entered empty.	lynn yauch (b) (4)	30 Sep 2020 14:20:04

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
User entered '0'	lynn yauch (b) (4)	30 Sep 2020 14:20:04

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, HLG T: 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, HLG T: 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
User entered 'un UNK 2013'	Pauline Jackson (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 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
User entered '0'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39

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
User entered 'No (N)'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39

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
User entered 'un UNK 2013'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39

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
User entered '0'	Pauline Jackson (b) (4)	19 Oct 2020 21:26:39

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered '27 Aug 2020'	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered '12:50'	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered '69.0' in	Cristina Puig (b) (4)	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

[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
User entered '190.0' lb	Cristina Puig (b) (4)	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 \(xxx.x\)](#)

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
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered empty.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	02 Sep 2020 23:59:00

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
User entered 'Yes (Y)'	Cristina Puig (b) (4)	02 Sep 2020 23:59:31

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
User entered '27 Aug 2020'	Cristina Puig (b) (4)	02 Sep 2020 23:59:31

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
User entered '27 Aug 2020'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41

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) (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)	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)	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
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:01:41

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
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:01:41

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
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41

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
User entered 'un UNK 1999'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41

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
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:01:41

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered 'No (N)'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered '1'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered '0'	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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
User entered empty.	Cristina Puig (b) (4)	03 Sep 2020 00:02:20

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)'	(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

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
	(b) (4)	

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)'	(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

[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)'	(b) (4) 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)'	(b) (4) 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)'	(b) (4) 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)'	(b) (4) 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)'	(b) (4) 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) (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

[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
	(b) (4)	

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)	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)	03 Sep 2020 00:03:35
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)	03 Sep 2020 00:03:07
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.	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

[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)	03 Sep 2020 00:03:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 00:03:35
User entered '72' 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)	03 Sep 2020 00:03:07
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

[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)	03 Sep 2020 00:03:35
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)	03 Sep 2020 00:03:07
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)	03 Sep 2020 00:03:35
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)	03 Sep 2020 00:03:07
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)	03 Sep 2020 00:03:35
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)	03 Sep 2020 00:03:07
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) (b) (4)	03 Sep 2020 00:04:11
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) (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

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)	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	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)	03 Sep 2020 00:03:07
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

[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)	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	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)	03 Sep 2020 00:03:07
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

[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

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)	03 Sep 2020 00:04:11
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)	03 Sep 2020 00:03:07
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)	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	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)	03 Sep 2020 00:03:07
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

[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)	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	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)	03 Sep 2020 00:03:07
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

[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)	03 Sep 2020 00:04:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	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)	03 Sep 2020 00:03:07
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

[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
	(b) (4)	

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.	(b) (4) 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)'	(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 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
	(b) (4)	

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.	(b) (4) Patrick Brooks (b) (4)	27 Aug 2020 22:02:48
	(b) (4)	

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'	(b) (4) Patrick Brooks (b) (4)	27 Aug 2020 22:02:48
	(b) (4)	

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'	(b) (4) Patrick Brooks (b) (4)	27 Aug 2020 22:02:48
	(b) (4)	

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
	(b) (4)	

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'	(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 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.	(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 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 '1'	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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' User entered '27 Aug 2020 17:09'	System	27 Aug 2020 22:09:16
	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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' User entered '02 Sep 2020 13:32'	System	02 Sep 2020 18:32:28
	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)'	(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

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.	(b) (4) Patrick Brooks (b) (4)	08 Sep 2020 22:22:40
	(b) (4)	

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)'	(b) (4) 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 '1'	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
	(b) (4)	

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)	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 '1'	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)'	(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

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'	(b) (4) Patrick Brooks (b) (4)	17 Sep 2020 21:42:29
	(b) (4)	

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.	(b) (4) Patrick Brooks (b) (4)	17 Sep 2020 21:42:29
	(b) (4)	

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)'	(b) (4) 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 '1'	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
	(b) (4)	

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)'	(b) (4) Chana Hines (b) (4) (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) (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

[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) (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)	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)	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)	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.	(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 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
	(b) (4)	

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) (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) (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) System	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) (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).	System	28 Sep 2020 17:04:54
User entered 'Left Arm (LEFT ARM)'	Chana Hines (b) (4) (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 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
	(b) (4)	

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) (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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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' User entered '28 Sep 2020 21:26'	System	29 Sep 2020 02:26:25
	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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)	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
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).	(b) (4)	08 Oct 2020 16:22:06
User entered '6 Sep 2020'	System	08 Oct 2020 16:22:06
	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) (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)'	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 '1'	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)'	(b) (4) 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'	(b) (4) Pauline Jackson (b) (4)	12 Oct 2020 20:50:57
	(b) (4)	

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)'	(b) (4) 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.	(b) (4) Pauline Jackson (b) (4)	12 Oct 2020 20:50:57
	(b) (4)	

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)'	(b) (4) 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)'	(b) (4) 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'	(b) (4) Pauline Jackson (b) (4)	19 Oct 2020 21:25:12
	(b) (4)	

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)'	(b) (4) 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.	(b) (4) Pauline Jackson (b) (4)	19 Oct 2020 21:25:12
	(b) (4)	

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)'	(b) (4) 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)	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)	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 '1'	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'	System	10 Nov 2020 14:15:46
User entered '10 Nov 2020 08:15:43'	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'	System	22 Nov 2020 12:36:46
User entered '22 Nov 2020 06:36:42'	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' 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'	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

Have you been exposed to someone with 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'	System	02 Jan 2021 07:10:38
User entered '02 Jan 2021 01:10:35'	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: '454cfb2-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: '454cfb2-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'	System	15 Mar 2021 17:31:29
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'	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

Have you been exposed to someone with 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'	System	24 Apr 2021 11:54:05
User entered 'No (N)'	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'	System	24 Apr 2021 11:54:05
User entered 'No (N)'	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'	(b) (4) Chana Hines (b) (4)	25 Nov 2020 22:40:54
	(b) (4)	

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.	(b) (4) Chana Hines (b) (4)	25 Nov 2020 22:40:54
	(b) (4)	

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.	(b) (4) 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 '1'	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)'	(b) (4) 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)'	(b) (4) 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.	(b) (4) Pamela Echols (b) (4) (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 '1'	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 '1'	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)'	(b) (4) 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)	16 Mar 2021 18:44:47
	(b) (4)	

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)'	(b) (4) 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.	(b) (4) 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.	(b) (4) Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20
	(b) (4)	

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.	(b) (4) 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.	(b) (4) Jacklyn Newton (b) (4)	30 Mar 2021 18:06:20
	(b) (4)	

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)	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)	16 Mar 2021 18:45:56
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 18:45:40
User entered 'No (N)'	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	(b) (4) lynn yauch (b) (4)	16 Mar 2021 18:45:56
User entered '15 Mar 2021'	(b) (4) lynn yauch (b) (4) (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)'	(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 (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)'	(b) (4) 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
User entered 'Yes (Y)'	Pamela Echols (b) (4)	08 Feb 2021 18:19:17

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
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:19:17

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
User entered 'Clinic (Clinic)'	Pamela Echols (b) (4)	08 Feb 2021 18:19:17

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
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43

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
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
User entered 'Yes (Y)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43

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
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
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43

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
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43

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
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43

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
User entered 'mRNA-1273 (mRNA-1273)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43

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
User entered 'No (N)'	Pamela Echols (b) (4)	08 Feb 2021 18:20:43

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
User entered 'Yes (Y)'	Pamela Echols (b) (4)	08 Feb 2021 18:21:25

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
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:21:25

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
User entered '10:49'	Pamela Echols (b) (4)	08 Feb 2021 18:21:25

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
User entered 'Yes (Y)'	Pamela Echols (b) (4)	08 Feb 2021 18:21:56

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
User entered '05 Feb 2021'	Pamela Echols (b) (4)	08 Feb 2021 18:21:56

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
User entered '10:57'	Pamela Echols (b) (4)	08 Feb 2021 18:21:56

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.	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

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)	30 Apr 2021 21:49:50
	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

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)'	(b) (4) lynn yauch (b) (4) (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 User entered 'amlodipine'	System lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:55:34 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
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

[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
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

[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 User signature succeeded.	System Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:34 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 User entered 'atorvastatin'	System lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:56:35 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
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

[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 User signature succeeded.	System Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:34 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 Coding entries removed.	System Lorine Cook (b) (4) (b) (4)	17 Nov 2020 20:27:05 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 Coding entries removed.	System lynn yauch (b) (4) (b) (4)	26 Oct 2020 15:59:21 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

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 User entered 'gabapentin'	System lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:57:36 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
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

[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).	(b) (4), (b) (6)	26 Oct 2020 05:25:00
User entered 'neuropathy'	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 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
User entered empty.	(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

[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
User entered empty.	(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

[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
User entered empty.	(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 (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
User entered empty.	(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

[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
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

[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
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

[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) (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

[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 User signature succeeded.	System Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:32 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 User entered 'lisinopril'	System lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:58:37 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
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

[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
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

[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
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

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 User signature succeeded.	System Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:35 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 User entered 'metoprolol'	System lynn yauch (b) (4) (b) (4)	15 Sep 2020 14:59:40 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
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

[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
User entered empty.	(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

[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
User entered empty.	(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

[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
User entered empty.	(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 (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) (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

[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
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

[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
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

[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 '1'	(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
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

[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
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

[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
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

[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 User signature succeeded.	System Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:27:35 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 User entered 'Insulin aspart protamine/insulin aspart'	System lynn yauch (b) (4) (b) (4)	15 Sep 2020 15:08:10 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 'IU (IU)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	01 Oct 2020 18:00:17
User entered 'Other (OTHER)'	(b) (4) lynn yauch (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 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)	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)	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)	26 Oct 2020 16:04:01
	(b) (4)	

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)	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)	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)	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
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

[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
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	
	Chana Hines (b) (4)	16 Dec 2020 21:14:26
	(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
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

[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)	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 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
	(b) (4)	
User entered '0'	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

[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
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

[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
User entered 'No (N)'	(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

[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) (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) (b) (4), (b) (6)	29 Jan 2021 10:03:33
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.'	lynn yauch (b) (4) (b) (4)	26 Jan 2021 20:49:34
answered with 'updated per query' (Site from DM). User entered 'application' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	26 Jan 2021 20:49:10
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.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:52:16
User entered '1 application to affected area (feet)'	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

[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
User entered empty.	(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

[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
User entered empty.	(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

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:27:31
User entered '25 Nov 2020'	(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

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
User entered empty.	(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

[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 21:22:39
	(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
User entered 'No (N)'	(b) (4) 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 '1'	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 '1'	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