

US3342023 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

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US3342023

Form: Participant Creation

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

[Participant ID](#)

US3342023

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

US3342023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Mar 2021 23:47:14

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Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3342023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Mar 2021 23:47:14

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Condition	CEDAR FEVER
Start date (dd MMM yyyy)	UN DEC 2000
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 DEC 2000
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2000
Start Year (derived)	2000
Stop Month and Year (derived)	DEC 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Condition	POST MENOPAUSAL
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)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:51 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 11:51
Height (<i>xxx.x</i>)	164 cm
Weight (<i>xxx.x</i>)	86.5 kg
BMI (<i>xxx.x</i>)	32.16092 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*) 11 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 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:47:14

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

WORKS FROM HOME

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:47:14

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185474

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 11:51
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:29
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:20:53

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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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 12:53 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 12:53

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	12:33 (24 HR)
Collection date and time (derived)	11 AUG 2020 12:33

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:35	11 AUG 2020 12:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 13:35

PC Open Date & Time

11 AUG 2020 13:13

PC Close Date & Time

11 AUG 2020 15:43

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 97.3 °F

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

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

PC Time Stamp	11 AUG 2020 19:18
PC Open Date & Time	11 AUG 2020 16:38
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 18:44

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 22:41

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 16:41

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

15 AUG 2020 16:45

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 17:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

17 AUG 2020 18:53

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 13:36

PC Open Date & Time

11 AUG 2020 13:13

PC Close Date & Time

11 AUG 2020 15:43

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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

12 AUG 2020 10:04

PC Open Date & Time

11 AUG 2020 16:38

PC Close Date & Time

12 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 18:45

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 22:42

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 16:42

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 16:45

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 17:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 18:54

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 13:37
PC Open Date & Time	11 AUG 2020 13:13
PC Close Date & Time	11 AUG 2020 15:43

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 10:05
PC Open Date & Time	11 AUG 2020 16:38
PC Close Date & Time	12 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

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 ☒

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EAB) (1725)

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 22:43
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 16:42
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

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 ☒

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 16:46
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

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 ☒

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EAB) (1725)

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US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 17:06
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 ☒

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:54
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3342023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:36
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:16
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3342023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 11:40

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

What was the frequency of the study treatment dosing? ONCE

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

US3342023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	11:21 (24 HR)
Collection date and time (derived)	8 SEP 2020 11:21

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:23	8 SEP 2020 11:23
Nasopharyngeal Swab 2	No		

US3342023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:27

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 14:30

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 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	08 SEP 2020 16:36
PC Open Date & Time	08 SEP 2020 15:25
PC Close Date & Time	09 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

10 SEP 2020 09:49

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 18:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 12:22

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:26

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 17:03

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

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

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

08 SEP 2020 12:28

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 14:30

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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

08 SEP 2020 16:37

PC Open Date & Time

08 SEP 2020 15:25

PC Close Date & Time

09 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 09:49

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 18:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:23

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:26

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 17:03

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:29
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 14:30

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 16:38
---------------	-------------------

PC Open Date & Time	08 SEP 2020 15:25
---------------------	-------------------

PC Close Date & Time	09 SEP 2020 11:59
----------------------	-------------------

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

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 ☒

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 09:50
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:21
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 2211

EAB) (1725)

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 2211

EAB) (1725)

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:26
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2211

EAB) (1725)

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:04
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 10:44
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

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.

US3342023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	11:08 (24 HR)
Collection date and time (derived)	6 OCT 2020 11:08

US3342023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:20:53

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 OCT 2020 00:02:19
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

19 OCT 2020 06:57:15

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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	26 OCT 2020 15:39:09
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 13:37:14
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 20:57:34
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

23 NOV 2020 12:54:55

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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	30 NOV 2020 06:47:48
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

07 DEC 2020 08:28:14

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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	14 DEC 2020 09:26:35
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 09:55:50

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 00:01:53

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

31 DEC 2020 02:26:46

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

07 JAN 2021 21:55:24

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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	14 JAN 2021 08:50:06
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

21 JAN 2021 08:05:54

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

28 JAN 2021 08:59:41

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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	04 FEB 2021 04:14:52
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 15:06:33

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 16:53:38
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

25 FEB 2021 09:34:10

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

04 MAR 2021 10:15:35

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 07:45:23

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

18 MAR 2021 10:23:24

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 07:16:31

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 APR 2021 03:36:40
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 APR 2021 00:09:36
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 14:21:29

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 08:40:22

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 07:22:44

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 AUG 2021 00:01
Patient Cloud Close Date & Time	23 AUG 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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°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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2022 00:01
Patient Cloud Close Date & Time	01 AUG 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission	_____
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3342023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:25:35

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 15:25:35

Generated On: 09 Jun 2021 17:06:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:24 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 10:24
Temperature (<i>xxx.x</i>)	98.0 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>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:25:35

Generated On: 09 Jun 2021 17:06:01

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.

US3342023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:25:35

Generated On: 09 Jun 2021 17:06:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 MAR 2021
Collection time (00:00-23:59)	10:47 (24 HR)
Collection date and time (derived)	10 MAR 2021 10:47

US3342023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:25:35

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 22:42:14

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 22:42:14

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342023

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:01

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"/>

US3342023

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:06:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342023

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

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3342023

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Date of updated informed consent (<i>dd MMM yyyy</i>)	5 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	5 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3342023

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Height	163.0 cm
Weight	88.5 kg
BMI (xxx.x)	33.30950

US3342023

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Height	163.0 cm
Weight	88.5 kg
BMI (xxx.x)	33.30950
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 JAN 2021
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 10:48
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3342023

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Height	163.0 cm
Weight	88.5 kg
BMI (xxx.x)	33.30950
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 JAN 2021
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 11:59
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3342023

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

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3342023

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

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 5 JAN 2021

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 11:29

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

US3342023

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 JAN 2021

Collection time (00:00-23:59)

11:20 (24 HR)

Collection date and time (derived)

05 JAN 2021 11:20

US3342023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 JAN 2021
Collection time (00:00 - 23:59)	11:22
Collection Date and Time (derived)	05 JAN 2021 11:22

US3342023

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

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3342023

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 FEB 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 10:25
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 FEB 2021
Time of assessment (00:00-23:59)	12:01 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 12:01
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3342023

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

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.

US3342023

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 01 FEB 2021

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 01 FEB 2021 11:29

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

US3342023

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:47:14

Generated On: 09 Jun 2021 17:06:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342023

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:24 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 10:24
Temperature (<i>xxx.x</i>)	98.0 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>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342023

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

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.

US3342023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 MAR 2021
Collection time (<i>00:00-23:59</i>)	10:47 (24 HR)
Collection date and time (derived)	10 MAR 2021 10:47

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 12 Apr 2021 15:25:35

Generated On: 09 Jun 2021 17:06:01

Visit Date	01 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:25:35

Generated On: 09 Jun 2021 17:06:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 FEB 2021
Collection time (00:00-23:59)	10:57 (24 HR)
Collection date and time (derived)	01 FEB 2021 10:57

US3342023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:29:44

Generated On: 09 Jun 2021 17:06:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

AEID	
Adverse event	RIGHT MENISCAL TEAR
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

AEID	
Adverse event	DEPRESSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

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

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

AEID

Adverse event

WORSENING OF SYMPTOMS:
HYPERTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 FEB 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 False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

AEID	USA-US203-2021-MRNA-1273-P30 1000013
Adverse event	R KNEE OSTEOARTHRITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 APR 2021
Hospital Discharge Date (dd MMM yyyy)	02 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

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

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

PT WENT TO THE ER ON 23
SEP2020 AND WAS DIAGNOSED
WITH BOTH A R KNEE
MENISCAL TEAR AND R KNEE
OSTEOARTHRITIS. PT WAS 1ST
TREATED FOR MENISCAL TEAR
BY PHYSICIAN (SEE MENISCAL
TEAR AE). AFTER HAVING
MENISCECTOMY PROCEDURE
PT WAS STILL HAVING PAIN TO
R KNEE AND DISCUSSED WITH
PHYSICIAN TOTAL R KNEE
REPLACEMENT. PT
ULTIMATELY DECIDED ON
REPLACEMENT ON 01APR2021.
PT STATED THAT THIS WAS AN
INPATIENT SURGERY. THIS AE
BECAME AN SAE.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

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

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Folder: Adverse Events

Form: Adverse Events (5)

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

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication CEDAR FEVER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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 DEC 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication RIGHT MENISCAL TEAR (AE)

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication CORTISONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT MENISCAL TEAR (AE)

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication RIGHT MENISCAL TEAR (AE)

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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)		18 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication AE: DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication AE: WORSENING SYMPTOMS
OF 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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)		16 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication R KNEE OSTEOARTHRITIS SAE

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

EVERY 4 HOURS

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication R KNEE OSTEOARTHRITIS SAE

Dose per administration 1

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

If dose unit is Other, specify SOFTGEL

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 EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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)		02 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication R KNEE OSTEOARTHRITIS SAE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

	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)		02 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 23:47:09

Generated On: 09 Jun 2021 17:06:01

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 NOV 2020	RIGHT MENISCUS SURGERY	Adverse Event	
01 APR 2021	TOTAL R KNEE REPLACEMENT	Adverse Event	

US3342023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:01

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3342023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:01

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 ☐

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

SAEID	USA-US203-2021-MRNA-1273-P301000013
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 15:25:34

Generated On: 09 Jun 2021 17:06:01

SAEID	USA-US203-2021-MRNA-1273-P301000013
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	PAUL
Investigator's Last Name	PICKRELL
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)	06/APR/2021 15:14
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

US3342023 (Prod: Tekton Research- Austin)

US3342023

Form: Participant Creation

Generated On: 09 Jun 2021 17:06:01

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:44:56
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'US3342023'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:59:26

US3342023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Brandi Chalman (b) (4)	11 Aug 2020 18:24:58

US3342023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '11 AUG 2020'	RWS_ENDPOINT	11 Aug 2020 16:59:26
	ENDPOINT (b) (4)	

US3342023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Clinic (Clinic)'	Brandi Chalman (b) (4)	11 Aug 2020 18:24:58

US3342023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'SCRN'	System	11 Aug 2020 18:24:58

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered (b) (6) 1950'	RWS_ENDPOINT	11 Aug 2020 16:59:27
	ENDPOINT (b) (4)	

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '69'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'YEARS'	System	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '69'	System	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Female (F)'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'I'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:01

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:16

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '11 Aug 2020'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'Aug 2020'	System	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '2020'	System	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Amendment 2 (2)'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Brandi Chalman (b) (4)	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Brandi Chalman (b) (4)	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Brandi Chalman (b) (4)	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	RWS_ENDPOINT	11 Aug 2020 16:59:26
	ENDPOINT (b) (4)	

US3342023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '1'	System	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Brandi Chalman (b) (4)	11 Aug 2020 18:24:50

US3342023

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:06:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:12:40

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Finger osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:50:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:50:01
User closed query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:15:48
Data point term sent to Coder	System	07 Oct 2020 16:15:42
User entered 'OSTEOARTHRITIS (Fingers of BILATERAL HANDS)' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	07 Oct 2020 16:15:15
Data point term sent to Coder	System	07 Oct 2020 15:57:01
User entered 'OSTEOARTHRITIS (Bilateral Hands)' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	07 Oct 2020 15:56:12
Query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4)	07 Oct 2020 15:55:22
Data point term sent to Coder	System	07 Oct 2020 15:54:56
Coding entries removed.	Darrell O'Brien (b) (4)	07 Oct 2020 15:54:45
User entered 'OSTEOARTHRITIS (Fingers)' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	07 Oct 2020 15:54:45

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:27:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 19:15:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	11 Aug 2020 19:15:18
Data point term sent to Coder	System	11 Aug 2020 19:14:05
User entered 'Osteoarthritis'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'UN UNK 2017'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'Jan 2017'	System	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '2017'	System	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered empty.	System	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered empty.	System	11 Aug 2020 19:13:18

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 19:16:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 19:16:11
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 19:15:10
User entered 'Hypertension'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'UN UNK 2017'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'Jan 2017'	System	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '2017'	System	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered empty.	System	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered empty.	System	11 Aug 2020 19:14:20

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 16:46:25
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 16:46:25
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 19:15:11
User entered 'Cedar fever'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'UN Dec 2000'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'UN Dec 2000'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'Dec 2000'	System	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '2000'	System	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'Dec 2000'	System	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '2000'	System	11 Aug 2020 19:15:03

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 16:39:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 16:39:57
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 16:38:40
User entered 'POST MENOPAUSAL'	Morgan Schulle (b) (4)	18 Sep 2020 16:38:36
	(b) (4)	

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'UN UNK 2000'	Morgan Schulle (b) (4)	18 Sep 2020 16:38:36
	(b) (4)	

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Morgan Schulle (b) (4)	18 Sep 2020 16:38:36
	(b) (4)	

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	18 Sep 2020 16:38:36
	(b) (4)	

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Morgan Schulle (b) (4)	18 Sep 2020 16:38:36
	(b) (4)	

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Morgan Schulle (b) (4)	18 Sep 2020 16:38:36
	(b) (4)	

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'Jan 2000'	System	18 Sep 2020 16:38:36

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '2000'	System	18 Sep 2020 16:38:36

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered empty.	System	18 Sep 2020 16:38:36

US3342023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered empty.	System	18 Sep 2020 16:38:36

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '11 Aug 2020'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '11:51'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered '11 Aug 2020 11:51'	System	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '164' cm	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23
DataPoint set to visible.	System	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '86.5' kg	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23
DataPoint set to visible.	System	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
Amendment Manager: User entered '32.16092'	System	16 Sep 2020 23:51:53
User entered '32.2'	System	11 Aug 2020 19:16:23
DataPoint set to visible.	System	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'kg/m2'	System	11 Aug 2020 19:16:23
DataPoint set to visible.	System	11 Aug 2020 18:25:34

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Stefanie Mott (b) (4)	24 Aug 2020 14:59:39
User entered '97.8' F	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty; reason for change Data Entry Error	Stefanie Mott (b) (4)	24 Aug 2020 14:59:39
User entered 'Oral (Oral)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Stefanie Mott (b) (4)	24 Aug 2020 14:59:39
User entered '78'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'bpm'	System	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Stefanie Mott (b) (4)	24 Aug 2020 14:59:39
User entered '12'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'breaths/min'	System	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Stefanie Mott (b) (4)	24 Aug 2020 14:59:39
User entered '127'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'mmHg'	System	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Stefanie Mott (b) (4)	24 Aug 2020 14:59:39
User entered '71'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User entered 'mmHg'	System	11 Aug 2020 19:16:23

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35

US3342023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35

US3342023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:49

US3342023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:16:41
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 15:54:07
User entered '11 Aug 2020'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:16:49

US3342023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '11 Aug 2020'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:17:48

US3342023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:17:48

US3342023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:01

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
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)	21 Sep 2020 13:10:41
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 'CONDITION ADDED TO MEDICAL HISTORY' (Site from DM).	Morgan Schulle (b) (4)	18 Sep 2020 16:39:26
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)	17 Sep 2020 06:38:42
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:17:48

US3342023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:01

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	11 Aug 2020 19:17:48

US3342023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	11 Aug 2020 19:17:48

US3342023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:01

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:17:48

US3342023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'UN UNK 2000'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:17:48

US3342023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:01

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:17:48

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

[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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

[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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

[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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'Works from home'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered 'I'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	11 Aug 2020 19:18:57

US3342023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:23:53

US3342023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11 Aug 2020'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:23:53

US3342023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Clinic (Clinic)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:23:53

US3342023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'VISIT1'	System	11 Aug 2020 18:23:53

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:24:37

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:36:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:36:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 17:24:37
User entered '185474' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:24:37

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:24:37

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

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)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:24:27

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

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)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:24:27

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:24:27

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:24:27

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:24:27

US3342023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:32:21

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Stefanie Mott (b) (4)	24 Aug 2020 15:00:07
User entered '164' cm	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Stefanie Mott (b) (4)	24 Aug 2020 15:00:07
User entered '86.5' kg	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Stefanie Mott (b) (4)	24 Aug 2020 15:00:07
User entered '164' cm	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Stefanie Mott (b) (4)	24 Aug 2020 15:00:07
User entered '86.5' kg	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11 Aug 2020'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11:51'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '11 Aug 2020 11:51'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '97.8' F	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Oral (Oral)'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '78'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'bpm'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '12'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'breaths/min'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '127'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '71'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Stefanie Mott (b) (4)	24 Aug 2020 15:00:07
User entered '164' cm	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Stefanie Mott (b) (4)	24 Aug 2020 15:00:07
User entered '86.5' kg	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11 Aug 2020'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User closed query 'Per CDM: The treatment time on the Exposure CRF is 12:53. The Vital Signs Post Dose Time of Assessment is 13:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM). Query 'Per CDM: The treatment time on the Exposure CRF is 12:53. The Vital Signs Post Dose Time of Assessment is 13:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' answered with 'time entered incorrectly; updated in edc' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 14:27:17
User entered '13:29' reason for change: Data Entry Error	Stefanie Mott (b) (4)	24 Aug 2020 14:58:09
User opened query 'Per CDM: The treatment time on the Exposure CRF is 12:53. The Vital Signs Post Dose Time of Assessment is 13:20. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM). User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per updated protocol 30 minute assessment required' (Site from System). User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). User entered '13:20'	(b) (4), (b) (6)	13 Aug 2020 05:15:01
	(b) (4), (b) (6)	13 Aug 2020 05:14:16
	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:36
		11 Aug 2020 19:22:01
	Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '11 Aug 2020 13:29'	System	24 Aug 2020 14:58:02
User entered '11 Aug 2020 13:20'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '98.1' F	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Oral (Oral)'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '75'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'bpm'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '13'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'breaths/min'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '120'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '69'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	11 Aug 2020 19:22:01

US3342023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 21:01:31
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	11 Aug 2020 19:23:02
	(b) (4)	
	Tiffany Lemuz (b) (4)	

US3342023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty; reason for change Data Entry Error	(b) (4)	21 Aug 2020 21:01:31
User entered '11 Aug 2020'	Eileen Euperio (b) (4)	21 Aug 2020 21:01:31
	(b) (4)	
	Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:02

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11 Aug 2020'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '12:53'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '11 Aug 2020 12:53'	System	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brandi Chalman (b) (4)	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'ONCE'	System	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 18:26:08

US3342023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:23

US3342023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11 Aug 2020'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:23

US3342023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 13:49:23
User entered '12:33' reason for change: Data Entry Error	System	13 Aug 2020 13:49:23
User opened query 'Data is required. Please provide.' (Site from System).	Tiffany Lemuz (b) (4)	13 Aug 2020 13:49:23
User entered empty.	System	11 Aug 2020 19:23:23
	Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:23

US3342023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '11 Aug 2020 12:33'	System	13 Aug 2020 13:49:23
User entered empty.	System	11 Aug 2020 19:23:23

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11 Aug 2020'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	13 Aug 2020 13:49:33
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	13 Aug 2020 13:49:33
User entered '12:35' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	13 Aug 2020 13:49:33
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	11 Aug 2020 19:23:34
User entered empty.	Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '11 Aug 2020 12:35'	System	13 Aug 2020 13:49:33
User entered empty.	System	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered empty.	System	11 Aug 2020 19:23:34

US3342023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	11 Aug 2020 19:23:44

US3342023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'I'	System	11 Aug 2020 19:23:44

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:35:07', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a435fe05-7be6-4a24-ada2-73b665c3e658'	System	11 Aug 2020 18:31:10
User entered 'Yes (Y)'	System	11 Aug 2020 18:31:10

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:35:18', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a435fe05-7be6-4a24-ada2-73b665c3e658'	System	11 Aug 2020 18:31:10
User entered '98.1'	System	11 Aug 2020 18:31:10

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:35:24', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a435fe05-7be6-4a24-ada2-73b665c3e658'	System	11 Aug 2020 18:31:10
User entered 'No (N)'	System	11 Aug 2020 18:31:10

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:35:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a435fe05-7be6-4a24-ada2-73b665c3e658'	System	11 Aug 2020 18:31:10
User entered '11 Aug 2020 13:35'	System	11 Aug 2020 18:31:10

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 13:13'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 15:43'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T19:17:37', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '61d2d3a4-aaa9-4068-9457-2b0a63b394ed'	System	12 Aug 2020 00:13:50
User entered 'Yes (Y)'	System	12 Aug 2020 00:13:50

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T19:17:54', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '61d2d3a4-aaa9-4068-9457-2b0a63b394ed' User entered '97.3'	System	12 Aug 2020 00:13:50
	System	12 Aug 2020 00:13:50

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T19:17:59', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '61d2d3a4-aaa9-4068-9457-2b0a63b394ed'	System	12 Aug 2020 00:13:50
User entered 'No (N)'	System	12 Aug 2020 00:13:50

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T19:18:17', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '61d2d3a4-aaa9-4068-9457-2b0a63b394ed'	System	12 Aug 2020 00:13:50
User entered '11 Aug 2020 19:18'	System	12 Aug 2020 00:13:50

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 16:38'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 2'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:43:47', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bd2a183e-fdf3-4ffb-9fa2-684ac1594b97'	System	12 Aug 2020 23:39:49
User entered 'Yes (Y)'	System	12 Aug 2020 23:39:49

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:43:59', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bd2a183e-fdf3-4ffb-9fa2-684ac1594b97'	System	12 Aug 2020 23:39:49
User entered '96.3'	System	12 Aug 2020 23:39:49

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:04', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bd2a183e-fdf3-4ffb-9fa2-684ac1594b97'	System	12 Aug 2020 23:39:49
User entered 'No (N)'	System	12 Aug 2020 23:39:49

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:16', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bd2a183e-fdf3-4ffb-9fa2-684ac1594b97'	System	12 Aug 2020 23:39:49
User entered '12 Aug 2020 18:44'	System	12 Aug 2020 23:39:49

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 3'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:41:15', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '18ba0081-cca1-478c-8b34-0823e44803a4'	System	14 Aug 2020 03:37:13
User entered 'Yes (Y)'	System	14 Aug 2020 03:37:13

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:41:26', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '18ba0081-cca1-478c-8b34-0823e44803a4'	System	14 Aug 2020 03:37:13
User entered '96.0'	System	14 Aug 2020 03:37:13

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:41:31', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '18ba0081-cca1-478c-8b34-0823e44803a4'	System	14 Aug 2020 03:37:13
User entered 'No (N)'	System	14 Aug 2020 03:37:13

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:41:39', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '18ba0081-cca1-478c-8b34-0823e44803a4'	System	14 Aug 2020 03:37:13
User entered '13 Aug 2020 22:41'	System	14 Aug 2020 03:37:13

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 4'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:41:31', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b6756553-ecb4-4cbe-a614-647f16c701fb'	System	14 Aug 2020 21:37:23
User entered 'Yes (Y)'	System	14 Aug 2020 21:37:23

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:41:42', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b6756553-ecb4-4cbe-a614-647f16c701fb'	System	14 Aug 2020 21:37:23
User entered '97.1'	System	14 Aug 2020 21:37:23

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:41:47', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b6756553-ecb4-4cbe-a614-647f16c701fb'	System	14 Aug 2020 21:37:23
User entered 'No (N)'	System	14 Aug 2020 21:37:23

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:41:53', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b6756553-ecb4-4cbe-a614-647f16c701fb'	System	14 Aug 2020 21:37:23
User entered '14 Aug 2020 16:41'	System	14 Aug 2020 21:37:23

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 5'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'eb0f498a-d8b5-4b84-8375-3d3296cab85d'	System	15 Aug 2020 21:40:48
User entered 'Yes (Y)'	System	15 Aug 2020 21:40:48

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:08', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'eb0f498a-d8b5-4b84-8375-3d3296cab85d'	System	15 Aug 2020 21:40:48
User entered '96.9'	System	15 Aug 2020 21:40:48

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:14', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'eb0f498a-d8b5-4b84-8375-3d3296cab85d'	System	15 Aug 2020 21:40:48
User entered 'No (N)'	System	15 Aug 2020 21:40:48

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:18', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'eb0f498a-d8b5-4b84-8375-3d3296cab85d'	System	15 Aug 2020 21:40:48
User entered '15 Aug 2020 16:45'	System	15 Aug 2020 21:40:48

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 6'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:04:56', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3eb2ed1-25ed-485f-b69e-c4aa2d5d2a1d'	System	16 Aug 2020 22:00:57
User entered 'Yes (Y)'	System	16 Aug 2020 22:00:57

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:20', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3eb2ed1-25ed-485f-b69e-c4aa2d5d2a1d'	System	16 Aug 2020 22:00:57
User entered '97.1'	System	16 Aug 2020 22:00:57

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:24', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3eb2ed1-25ed-485f-b69e-c4aa2d5d2a1d'	System	16 Aug 2020 22:00:57
User entered 'No (N)'	System	16 Aug 2020 22:00:57

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:28', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3eb2ed1-25ed-485f-b69e-c4aa2d5d2a1d'	System	16 Aug 2020 22:00:57
User entered '16 Aug 2020 17:05'	System	16 Aug 2020 22:00:57

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 7'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:53:20', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '74f7713e-b48a-4717-8415-c68885925554'	System	17 Aug 2020 23:49:05
User entered 'Yes (Y)'	System	17 Aug 2020 23:49:05

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:53:28', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '74f7713e-b48a-4717-8415-c68885925554'	System	17 Aug 2020 23:49:05
User entered '96.9'	System	17 Aug 2020 23:49:05

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:53:32', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '74f7713e-b48a-4717-8415-c68885925554'	System	17 Aug 2020 23:49:05
User entered 'No (N)'	System	17 Aug 2020 23:49:05

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:53:36', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '74f7713e-b48a-4717-8415-c68885925554'	System	17 Aug 2020 23:49:05
User entered '17 Aug 2020 18:53'	System	17 Aug 2020 23:49:05

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:35:50', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '88aea1be-5e37-473c-b8aa-a9ef8aff1001'	System	11 Aug 2020 18:32:25
User entered 'None (1)'	System	11 Aug 2020 18:32:25

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:36:25', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '88aea1be-5e37-473c-b8aa-a9ef8aff1001'	System	11 Aug 2020 18:32:25
User entered 'No (N)'	System	11 Aug 2020 18:32:25

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:36:32', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '88aea1be-5e37-473c-b8aa-a9ef8aff1001'	System	11 Aug 2020 18:32:25
User entered 'No (N)'	System	11 Aug 2020 18:32:25

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:36:40', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '88aea1be-5e37-473c-b8aa-a9ef8aff1001'	System	11 Aug 2020 18:32:25
User entered 'None (1)'	System	11 Aug 2020 18:32:25

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:36:51', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '88aea1be-5e37-473c-b8aa-a9ef8aff1001'	System	11 Aug 2020 18:32:25
User entered '11 Aug 2020 13:36'	System	11 Aug 2020 18:32:25

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 13:13'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 15:43'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:03:46', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9087d4ac-707e-4a3a-a31b-3a7882193b85'	System	12 Aug 2020 15:00:10
User entered 'None (1)'	System	12 Aug 2020 15:00:10

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:03:50', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9087d4ac-707e-4a3a-a31b-3a7882193b85'	System	12 Aug 2020 15:00:10
User entered 'No (N)'	System	12 Aug 2020 15:00:10

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:03:54', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9087d4ac-707e-4a3a-a31b-3a7882193b85'	System	12 Aug 2020 15:00:10
User entered 'No (N)'	System	12 Aug 2020 15:00:10

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:03', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9087d4ac-707e-4a3a-a31b-3a7882193b85'	System	12 Aug 2020 15:00:10
User entered 'None (1)'	System	12 Aug 2020 15:00:10

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:17', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9087d4ac-707e-4a3a-a31b-3a7882193b85'	System	12 Aug 2020 15:00:10
User entered '12 Aug 2020 10:04'	System	12 Aug 2020 15:00:10

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 16:38'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 2'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:45:08', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3fbfb89-c3d5-4907-a848-a81a1aac8a01'	System	12 Aug 2020 23:41:04
User entered 'None (1)'	System	12 Aug 2020 23:41:04

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:45:12', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3fbfb89-c3d5-4907-a848-a81a1aac8a01'	System	12 Aug 2020 23:41:04
User entered 'No (N)'	System	12 Aug 2020 23:41:04

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:45:18', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3fbfb89-c3d5-4907-a848-a81a1aac8a01'	System	12 Aug 2020 23:41:04
User entered 'No (N)'	System	12 Aug 2020 23:41:04

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:45:23', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3fbfb89-c3d5-4907-a848-a81a1aac8a01'	System	12 Aug 2020 23:41:04
User entered 'None (1)'	System	12 Aug 2020 23:41:04

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:45:28', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c3fbfb89-c3d5-4907-a848-a81a1aac8a01'	System	12 Aug 2020 23:41:04
User entered '12 Aug 2020 18:45'	System	12 Aug 2020 23:41:04

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 3'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:42:24', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b165a0f5-6308-4e05-99b0-0cf423f92f19'	System	14 Aug 2020 03:38:26
User entered 'None (1)'	System	14 Aug 2020 03:38:26

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:42:29', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b165a0f5-6308-4e05-99b0-0cf423f92f19'	System	14 Aug 2020 03:38:26
User entered 'No (N)'	System	14 Aug 2020 03:38:26

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:42:37', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b165a0f5-6308-4e05-99b0-0cf423f92f19'	System	14 Aug 2020 03:38:26
User entered 'No (N)'	System	14 Aug 2020 03:38:26

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:42:46', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b165a0f5-6308-4e05-99b0-0cf423f92f19'	System	14 Aug 2020 03:38:26
User entered 'None (1)'	System	14 Aug 2020 03:38:26

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:42:51', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b165a0f5-6308-4e05-99b0-0cf423f92f19'	System	14 Aug 2020 03:38:26
User entered '13 Aug 2020 22:42'	System	14 Aug 2020 03:38:26

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 4'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f6ce36a8-034e-4cca-83a5-c187a107a9bd'	System	14 Aug 2020 21:37:47
User entered 'None (1)'	System	14 Aug 2020 21:37:47

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:04', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f6ce36a8-034e-4cca-83a5-c187a107a9bd'	System	14 Aug 2020 21:37:47
User entered 'No (N)'	System	14 Aug 2020 21:37:47

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:08', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f6ce36a8-034e-4cca-83a5-c187a107a9bd'	System	14 Aug 2020 21:37:47
User entered 'No (N)'	System	14 Aug 2020 21:37:47

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:13', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f6ce36a8-034e-4cca-83a5-c187a107a9bd'	System	14 Aug 2020 21:37:47
User entered 'None (1)'	System	14 Aug 2020 21:37:47

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:17', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f6ce36a8-034e-4cca-83a5-c187a107a9bd'	System	14 Aug 2020 21:37:47
User entered '14 Aug 2020 16:42'	System	14 Aug 2020 21:37:47

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 5'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:27', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '44038501-b6f4-4b40-a491-fde54509385c'	System	15 Aug 2020 21:41:12
User entered 'None (1)'	System	15 Aug 2020 21:41:12

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:32', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '44038501-b6f4-4b40-a491-fde54509385c'	System	15 Aug 2020 21:41:12
User entered 'No (N)'	System	15 Aug 2020 21:41:12

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:35', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '44038501-b6f4-4b40-a491-fde54509385c'	System	15 Aug 2020 21:41:12
User entered 'No (N)'	System	15 Aug 2020 21:41:12

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '44038501-b6f4-4b40-a491-fde54509385c'	System	15 Aug 2020 21:41:12
User entered 'None (1)'	System	15 Aug 2020 21:41:12

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:42', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '44038501-b6f4-4b40-a491-fde54509385c'	System	15 Aug 2020 21:41:12
User entered '15 Aug 2020 16:45'	System	15 Aug 2020 21:41:12

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 6'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:34', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e77f561a-ffff-41cc-b2a4-eded3eedfeb7'	System	16 Aug 2020 22:01:19
User entered 'None (1)'	System	16 Aug 2020 22:01:19

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e77f561a-ffff-41cc-b2a4-eded3eedfeb7'	System	16 Aug 2020 22:01:19
User entered 'No (N)'	System	16 Aug 2020 22:01:19

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:42', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e77f561a-ffff-41cc-b2a4-eded3eedfeb7'	System	16 Aug 2020 22:01:19
User entered 'No (N)'	System	16 Aug 2020 22:01:19

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:46', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e77f561a-ffff-41cc-b2a4-eded3eedfeb7'	System	16 Aug 2020 22:01:19
User entered 'None (1)'	System	16 Aug 2020 22:01:19

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:49', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e77f561a-ffff-41cc-b2a4-eded3eedfeb7'	System	16 Aug 2020 22:01:19
User entered '16 Aug 2020 17:05'	System	16 Aug 2020 22:01:19

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 7'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:53:49', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0a1058b8-1ce7-40dc-9a9d-0b85cab31949'	System	17 Aug 2020 23:49:38
User entered 'None (1)'	System	17 Aug 2020 23:49:38

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:53:52', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0a1058b8-1ce7-40dc-9a9d-0b85cab31949'	System	17 Aug 2020 23:49:38
User entered 'No (N)'	System	17 Aug 2020 23:49:38

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:53:56', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0a1058b8-1ce7-40dc-9a9d-0b85cab31949'	System	17 Aug 2020 23:49:38
User entered 'No (N)'	System	17 Aug 2020 23:49:38

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:02', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0a1058b8-1ce7-40dc-9a9d-0b85cab31949'	System	17 Aug 2020 23:49:38
User entered 'None (1)'	System	17 Aug 2020 23:49:38

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:09', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0a1058b8-1ce7-40dc-9a9d-0b85cab31949'	System	17 Aug 2020 23:49:38
User entered '17 Aug 2020 18:54'	System	17 Aug 2020 23:49:38

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:37:05', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'd15dbaa0-a008-4cd0-8b2e-a3261463089d'	System	11 Aug 2020 18:33:11
User entered 'None (0)'	System	11 Aug 2020 18:33:11

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:37:14', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'd15dbaa0-a008-4cd0-8b2e-a3261463089d'	System	11 Aug 2020 18:33:11
User entered 'None (0)'	System	11 Aug 2020 18:33:11

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:37:17', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'd15dbaa0-a008-4cd0-8b2e-a3261463089d'	System	11 Aug 2020 18:33:11
User entered 'None (0)'	System	11 Aug 2020 18:33:11

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:37:21', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'd15dbaa0-a008-4cd0-8b2e-a3261463089d'	System	11 Aug 2020 18:33:11
User entered 'None (0)'	System	11 Aug 2020 18:33:11

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:37:23', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'd15dbaa0-a008-4cd0-8b2e-a3261463089d'	System	11 Aug 2020 18:33:11
User entered 'None (0)'	System	11 Aug 2020 18:33:11

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:37:26', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'd15dbaa0-a008-4cd0-8b2e-a3261463089d'	System	11 Aug 2020 18:33:11
User entered 'None (0)'	System	11 Aug 2020 18:33:11

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:37:32', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'd15dbaa0-a008-4cd0-8b2e-a3261463089d'	System	11 Aug 2020 18:33:11
User entered 'No (N)'	System	11 Aug 2020 18:33:11

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-11T13:37:36', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'd15dbaa0-a008-4cd0-8b2e-a3261463089d'	System	11 Aug 2020 18:33:11
User entered '11 Aug 2020 13:37'	System	11 Aug 2020 18:33:11

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 13:13'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 15:43'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:31', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '19016de2-1d71-4a26-a146-97536e7a7bb0'	System	12 Aug 2020 15:00:39
User entered 'None (0)'	System	12 Aug 2020 15:00:39

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:34', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '19016de2-1d71-4a26-a146-97536e7a7bb0'	System	12 Aug 2020 15:00:39
User entered 'None (0)'	System	12 Aug 2020 15:00:39

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '19016de2-1d71-4a26-a146-97536e7a7bb0'	System	12 Aug 2020 15:00:39
User entered 'None (0)'	System	12 Aug 2020 15:00:39

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:42', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '19016de2-1d71-4a26-a146-97536e7a7bb0'	System	12 Aug 2020 15:00:39
User entered 'None (0)'	System	12 Aug 2020 15:00:39

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:45', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '19016de2-1d71-4a26-a146-97536e7a7bb0'	System	12 Aug 2020 15:00:39
User entered 'None (0)'	System	12 Aug 2020 15:00:39

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:48', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '19016de2-1d71-4a26-a146-97536e7a7bb0'	System	12 Aug 2020 15:00:39
User entered 'None (0)'	System	12 Aug 2020 15:00:39

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:04:55', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '19016de2-1d71-4a26-a146-97536e7a7bb0'	System	12 Aug 2020 15:00:39
User entered 'No (N)'	System	12 Aug 2020 15:00:39

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T10:05:05', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '19016de2-1d71-4a26-a146-97536e7a7bb0'	System	12 Aug 2020 15:00:39
User entered '12 Aug 2020 10:05'	System	12 Aug 2020 15:00:39

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Aug 2020 16:38'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 2'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:27', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '39c0ae8c-a8de-49d3-b94e-f0c37484790d'	System	12 Aug 2020 23:40:32
User entered 'None (0)'	System	12 Aug 2020 23:40:32

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:30', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '39c0ae8c-a8de-49d3-b94e-f0c37484790d'	System	12 Aug 2020 23:40:32
User entered 'None (0)'	System	12 Aug 2020 23:40:32

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:34', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '39c0ae8c-a8de-49d3-b94e-f0c37484790d'	System	12 Aug 2020 23:40:32
User entered 'None (0)'	System	12 Aug 2020 23:40:32

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '39c0ae8c-a8de-49d3-b94e-f0c37484790d'	System	12 Aug 2020 23:40:32
User entered 'None (0)'	System	12 Aug 2020 23:40:32

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:41', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '39c0ae8c-a8de-49d3-b94e-f0c37484790d'	System	12 Aug 2020 23:40:32
User entered 'None (0)'	System	12 Aug 2020 23:40:32

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:45', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '39c0ae8c-a8de-49d3-b94e-f0c37484790d'	System	12 Aug 2020 23:40:32
User entered 'None (0)'	System	12 Aug 2020 23:40:32

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:52', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '39c0ae8c-a8de-49d3-b94e-f0c37484790d'	System	12 Aug 2020 23:40:32
User entered 'No (N)'	System	12 Aug 2020 23:40:32

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-12T18:44:56', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '39c0ae8c-a8de-49d3-b94e-f0c37484790d'	System	12 Aug 2020 23:40:32
User entered '12 Aug 2020 18:44'	System	12 Aug 2020 23:40:32

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 3'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:42:57', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '286fd035-fea9-43ab-9ff7-414c8cf4e3d5'	System	14 Aug 2020 03:38:57
User entered 'None (0)'	System	14 Aug 2020 03:38:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:43:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '286fd035-fea9-43ab-9ff7-414c8cf4e3d5'	System	14 Aug 2020 03:38:57
User entered 'None (0)'	System	14 Aug 2020 03:38:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:43:03', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '286fd035-fea9-43ab-9ff7-414c8cf4e3d5'	System	14 Aug 2020 03:38:57
User entered 'None (0)'	System	14 Aug 2020 03:38:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:43:06', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '286fd035-fea9-43ab-9ff7-414c8cf4e3d5'	System	14 Aug 2020 03:38:57
User entered 'None (0)'	System	14 Aug 2020 03:38:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:43:10', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '286fd035-fea9-43ab-9ff7-414c8cf4e3d5'	System	14 Aug 2020 03:38:57
User entered 'None (0)'	System	14 Aug 2020 03:38:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:43:13', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '286fd035-fea9-43ab-9ff7-414c8cf4e3d5'	System	14 Aug 2020 03:38:57
User entered 'None (0)'	System	14 Aug 2020 03:38:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:43:20', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '286fd035-fea9-43ab-9ff7-414c8cf4e3d5'	System	14 Aug 2020 03:38:57
User entered 'No (N)'	System	14 Aug 2020 03:38:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-13T22:43:24', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '286fd035-fea9-43ab-9ff7-414c8cf4e3d5'	System	14 Aug 2020 03:38:57
User entered '13 Aug 2020 22:43'	System	14 Aug 2020 03:38:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 4'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:22', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cfda5c4d-8eb5-4c04-ac7c-45972494e745'	System	14 Aug 2020 21:38:28
User entered 'None (0)'	System	14 Aug 2020 21:38:28

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:30', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cfda5c4d-8eb5-4c04-ac7c-45972494e745'	System	14 Aug 2020 21:38:28
User entered 'None (0)'	System	14 Aug 2020 21:38:28

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cfda5c4d-8eb5-4c04-ac7c-45972494e745'	System	14 Aug 2020 21:38:28
User entered 'None (0)'	System	14 Aug 2020 21:38:28

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cfda5c4d-8eb5-4c04-ac7c-45972494e745'	System	14 Aug 2020 21:38:28
User entered 'None (0)'	System	14 Aug 2020 21:38:28

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:41', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cfda5c4d-8eb5-4c04-ac7c-45972494e745'	System	14 Aug 2020 21:38:28
User entered 'None (0)'	System	14 Aug 2020 21:38:28

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:44', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cfda5c4d-8eb5-4c04-ac7c-45972494e745'	System	14 Aug 2020 21:38:28
User entered 'None (0)'	System	14 Aug 2020 21:38:28

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:51', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cfda5c4d-8eb5-4c04-ac7c-45972494e745'	System	14 Aug 2020 21:38:28
User entered 'No (N)'	System	14 Aug 2020 21:38:28

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-14T16:42:56', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cfda5c4d-8eb5-4c04-ac7c-45972494e745'	System	14 Aug 2020 21:38:28
User entered '14 Aug 2020 16:42'	System	14 Aug 2020 21:38:28

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 5'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:45:59', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bfdbee21-1482-48e3-851d-eeacf93eda64'	System	15 Aug 2020 21:41:53
User entered 'None (0)'	System	15 Aug 2020 21:41:53

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:46:03', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bfdbee21-1482-48e3-851d-eeacf93eda64'	System	15 Aug 2020 21:41:53
User entered 'None (0)'	System	15 Aug 2020 21:41:53

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:46:06', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bfdbee21-1482-48e3-851d-eeacf93eda64'	System	15 Aug 2020 21:41:53
User entered 'None (0)'	System	15 Aug 2020 21:41:53

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:46:09', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bfdbee21-1482-48e3-851d-eeacf93eda64'	System	15 Aug 2020 21:41:53
User entered 'None (0)'	System	15 Aug 2020 21:41:53

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:46:13', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bfdbee21-1482-48e3-851d-eeacf93eda64'	System	15 Aug 2020 21:41:53
User entered 'None (0)'	System	15 Aug 2020 21:41:53

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:46:16', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bfdbee21-1482-48e3-851d-eeacf93eda64'	System	15 Aug 2020 21:41:53
User entered 'None (0)'	System	15 Aug 2020 21:41:53

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:46:21', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bfdbee21-1482-48e3-851d-eeacf93eda64'	System	15 Aug 2020 21:41:53
User entered 'No (N)'	System	15 Aug 2020 21:41:53

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-15T16:46:25', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bfdbee21-1482-48e3-851d-eeacf93eda64'	System	15 Aug 2020 21:41:53
User entered '15 Aug 2020 16:46'	System	15 Aug 2020 21:41:53

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 6'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:05:55', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0aaf8ef7-4682-4114-b80b-1e59535a1896'	System	16 Aug 2020 22:01:57
User entered 'None (0)'	System	16 Aug 2020 22:01:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:06:05', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0aaf8ef7-4682-4114-b80b-1e59535a1896'	System	16 Aug 2020 22:01:57
User entered 'None (0)'	System	16 Aug 2020 22:01:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:06:08', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0aaf8ef7-4682-4114-b80b-1e59535a1896'	System	16 Aug 2020 22:01:57
User entered 'None (0)'	System	16 Aug 2020 22:01:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:06:12', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0aaf8ef7-4682-4114-b80b-1e59535a1896'	System	16 Aug 2020 22:01:57
User entered 'None (0)'	System	16 Aug 2020 22:01:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:06:15', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0aaf8ef7-4682-4114-b80b-1e59535a1896'	System	16 Aug 2020 22:01:57
User entered 'None (0)'	System	16 Aug 2020 22:01:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:06:18', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0aaf8ef7-4682-4114-b80b-1e59535a1896'	System	16 Aug 2020 22:01:57
User entered 'None (0)'	System	16 Aug 2020 22:01:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:06:23', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0aaf8ef7-4682-4114-b80b-1e59535a1896'	System	16 Aug 2020 22:01:57
User entered 'No (N)'	System	16 Aug 2020 22:01:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-16T17:06:27', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '0aaf8ef7-4682-4114-b80b-1e59535a1896'	System	16 Aug 2020 22:01:57
User entered '16 Aug 2020 17:06'	System	16 Aug 2020 22:01:57

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 7'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:15', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9f34902-877e-4fbc-bd4a-f654277ccf87'	System	17 Aug 2020 23:50:07
User entered 'None (0)'	System	17 Aug 2020 23:50:07

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:18', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9f34902-877e-4fbc-bd4a-f654277ccf87'	System	17 Aug 2020 23:50:07
User entered 'None (0)'	System	17 Aug 2020 23:50:07

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:21', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9f34902-877e-4fbc-bd4a-f654277ccf87'	System	17 Aug 2020 23:50:07
User entered 'None (0)'	System	17 Aug 2020 23:50:07

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:24', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9f34902-877e-4fbc-bd4a-f654277ccf87'	System	17 Aug 2020 23:50:07
User entered 'None (0)'	System	17 Aug 2020 23:50:07

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:27', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9f34902-877e-4fbc-bd4a-f654277ccf87'	System	17 Aug 2020 23:50:07
User entered 'None (0)'	System	17 Aug 2020 23:50:07

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:30', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9f34902-877e-4fbc-bd4a-f654277ccf87'	System	17 Aug 2020 23:50:07
User entered 'None (0)'	System	17 Aug 2020 23:50:07

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:34', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9f34902-877e-4fbc-bd4a-f654277ccf87'	System	17 Aug 2020 23:50:07
User entered 'No (N)'	System	17 Aug 2020 23:50:07

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-08-17T18:54:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9f34902-877e-4fbc-bd4a-f654277ccf87'	System	17 Aug 2020 23:50:07
User entered '17 Aug 2020 18:54'	System	17 Aug 2020 23:50:07

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:26:08

US3342023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	26 Aug 2020 14:31:13

US3342023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '18 Aug 2020'	Ethan Shotton (b) (4)	26 Aug 2020 14:31:13

US3342023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	26 Aug 2020 14:31:13

US3342023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Ethan Shotton (b) (4)	26 Aug 2020 14:31:13

US3342023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	26 Aug 2020 14:31:18

US3342023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'I'	System	26 Aug 2020 14:31:18

US3342023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	26 Aug 2020 14:31:33

US3342023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '26 Aug 2020'	Ethan Shotton (b) (4)	26 Aug 2020 14:31:33

US3342023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	26 Aug 2020 14:31:33

US3342023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Ethan Shotton (b) (4)	26 Aug 2020 14:31:33

US3342023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	26 Aug 2020 14:31:36

US3342023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'I'	System	26 Aug 2020 14:31:36

US3342023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	01 Sep 2020 20:26:38

US3342023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '1 Sep 2020'	Ethan Shotton (b) (4)	01 Sep 2020 20:26:38

US3342023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	01 Sep 2020 20:26:38

US3342023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Ethan Shotton (b) (4)	01 Sep 2020 20:26:38

US3342023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	01 Sep 2020 20:26:42

US3342023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'I'	System	01 Sep 2020 20:26:42

US3342023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	08 Sep 2020 15:54:07

US3342023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '08 Sep 2020'	Darrell O'Brien (b) (4)	08 Sep 2020 15:54:07

US3342023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4)	08 Sep 2020 15:54:07

US3342023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'VISIT2'	System	08 Sep 2020 15:54:07

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '10:36'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '8 Sep 2020 10:36'	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '68'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'bpm'	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'breaths/min'	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '145'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '82'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 19:29:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 19:29:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	08 Sep 2020 19:29:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 17:07:27
User entered empty.	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '8 Sep 2020' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 19:29:35
User entered empty.	Morgan Schulle (b) (4)	08 Sep 2020 17:07:27
	(b) (4), (b) (6)	

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '12:16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:05:30
User entered '12:13' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	08 Sep 2020 19:29:35
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '8 Sep 2020 12:16'	System	10 Sep 2020 13:05:30
User entered '8 Sep 2020 12:13'	System	08 Sep 2020 19:29:35
User entered empty.	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User closed query 'Per CDM: Please consider removing "0" before 097.7. Thank you!' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:25:24
Query 'Per CDM: Please consider removing "0" before 097.7. Thank you! ' answered with 'Temperature has been corrected.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	20 Nov 2020 14:31:58
User entered '97.7' F reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	20 Nov 2020 14:31:48
User opened query 'Per CDM: Please consider removing "0" before 097.7. Thank you!' ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:03:42
User entered '097.7' F reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	08 Sep 2020 19:29:35
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 19:29:35
User entered empty.	Morgan Schulle (b) (4)	08 Sep 2020 17:07:27
	(b) (4), (b) (6)	

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '61' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 19:29:35
User entered empty.	Morgan Schulle (b) (4)	08 Sep 2020 17:07:27
	(b) (4), (b) (6)	

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'bpm'	System	08 Sep 2020 19:29:35
User entered empty.	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '16' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 19:29:35
User entered empty.	Morgan Schulle (b) (4)	08 Sep 2020 17:07:27
	(b) (4), (b) (6)	

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'breaths/min'	System	08 Sep 2020 19:29:35
User entered empty.	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '138' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 19:29:35
User entered empty.	Morgan Schulle (b) (4)	08 Sep 2020 17:07:27
	(b) (4), (b) (6)	

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	08 Sep 2020 19:29:35
User entered empty.	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '82' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 19:29:35
User entered empty.	Morgan Schulle (b) (4)	08 Sep 2020 17:07:27
	(b) (4), (b) (6)	

US3342023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	08 Sep 2020 19:29:35
User entered empty.	System	08 Sep 2020 17:07:27

US3342023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	08 Sep 2020 15:54:23

US3342023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '08 Sep 2020'	Darrell O'Brien (b) (4)	08 Sep 2020 15:54:23

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11:40'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '8 Sep 2020 11:40'	System	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'ONCE'	System	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 17:21:24

US3342023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	09 Sep 2020 15:22:55

US3342023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '8 Sep 2020'	Morgan Schulle (b) (4)	09 Sep 2020 15:22:55

US3342023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11:21'	Morgan Schulle (b) (4)	09 Sep 2020 15:22:55

US3342023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '8 Sep 2020 11:21'	System	09 Sep 2020 15:22:55

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '8 Sep 2020'	Morgan Schulle (b) (4)	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11:23'	Morgan Schulle (b) (4)	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '8 Sep 2020 11:23'	System	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)'	Morgan Schulle (b) (4)	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Morgan Schulle (b) (4)	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered empty.	System	09 Sep 2020 15:23:11

US3342023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	08 Sep 2020 19:29:53

US3342023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '1'	System	08 Sep 2020 19:29:53

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:27:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b505bd00-4694-42e8-bc6e-2e1c89a9f392'	System	08 Sep 2020 17:22:50
User entered 'Yes (Y)'	System	08 Sep 2020 17:22:50

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:27:18', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b505bd00-4694-42e8-bc6e-2e1c89a9f392'	System	08 Sep 2020 17:22:50
User entered '97.7'	System	08 Sep 2020 17:22:50

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:27:23', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b505bd00-4694-42e8-bc6e-2e1c89a9f392'	System	08 Sep 2020 17:22:50
User entered 'No (N)'	System	08 Sep 2020 17:22:50

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:27:43', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b505bd00-4694-42e8-bc6e-2e1c89a9f392'	System	08 Sep 2020 17:22:50
User entered '08 Sep 2020 12:27'	System	08 Sep 2020 17:22:50

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 14:30'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:36:35', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '21c636ba-d88a-4ded-9596-3a7c3289dfd8'	System	08 Sep 2020 21:32:02
User entered 'Yes (Y)'	System	08 Sep 2020 21:32:02

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:36:46', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '21c636ba-d88a-4ded-9596-3a7c3289dfd8'	System	08 Sep 2020 21:32:02
User entered '96.8'	System	08 Sep 2020 21:32:02

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:36:50', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '21c636ba-d88a-4ded-9596-3a7c3289dfd8'	System	08 Sep 2020 21:32:02
User entered 'No (N)'	System	08 Sep 2020 21:32:02

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:36:54', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '21c636ba-d88a-4ded-9596-3a7c3289dfd8'	System	08 Sep 2020 21:32:02
User entered '08 Sep 2020 16:36'	System	08 Sep 2020 21:32:02

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 15:25'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 2'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:48:37', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4c79255a-0fa2-48eb-be92-476d976f2c20'	System	10 Sep 2020 14:44:15
User entered 'Yes (Y)'	System	10 Sep 2020 14:44:15

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:48:59', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4c79255a-0fa2-48eb-be92-476d976f2c20'	System	10 Sep 2020 14:44:15
User entered '96.8'	System	10 Sep 2020 14:44:15

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:05', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4c79255a-0fa2-48eb-be92-476d976f2c20'	System	10 Sep 2020 14:44:15
User entered 'No (N)'	System	10 Sep 2020 14:44:15

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:09', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4c79255a-0fa2-48eb-be92-476d976f2c20'	System	10 Sep 2020 14:44:15
User entered '10 Sep 2020 09:49'	System	10 Sep 2020 14:44:15

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 3'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:19:45', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b3ddf6e6-0560-49d9-97b9-d0ca10abfeca'	System	10 Sep 2020 23:15:23
User entered 'Yes (Y)'	System	10 Sep 2020 23:15:23

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:05', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b3ddf6e6-0560-49d9-97b9-d0ca10abfeca' User entered '97.1'	System	10 Sep 2020 23:15:23
	System	10 Sep 2020 23:15:23

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:09', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b3ddf6e6-0560-49d9-97b9-d0ca10abfeca'	System	10 Sep 2020 23:15:23
User entered 'No (N)'	System	10 Sep 2020 23:15:23

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:18', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b3ddf6e6-0560-49d9-97b9-d0ca10abfeca'	System	10 Sep 2020 23:15:23
User entered '10 Sep 2020 18:20'	System	10 Sep 2020 23:15:23

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 4'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:22:22', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ab0e22a2-dd9f-4b5c-9763-26b11b38f84f'	System	11 Sep 2020 17:17:43
User entered 'Yes (Y)'	System	11 Sep 2020 17:17:43

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:22:29', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ab0e22a2-dd9f-4b5c-9763-26b11b38f84f'	System	11 Sep 2020 17:17:43
User entered '96.1'	System	11 Sep 2020 17:17:43

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:22:35', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ab0e22a2-dd9f-4b5c-9763-26b11b38f84f'	System	11 Sep 2020 17:17:43
User entered 'No (N)'	System	11 Sep 2020 17:17:43

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:22:39', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ab0e22a2-dd9f-4b5c-9763-26b11b38f84f'	System	11 Sep 2020 17:17:43
User entered '11 Sep 2020 12:22'	System	11 Sep 2020 17:17:43

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 5'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:24:21', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e78cf73-ce45-4660-822b-21dae65976ca'	System	12 Sep 2020 17:21:02
User entered 'Yes (Y)'	System	12 Sep 2020 17:21:02

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:25:53', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e78cf73-ce45-4660-822b-21dae65976ca'	System	12 Sep 2020 17:21:02
User entered '98.1'	System	12 Sep 2020 17:21:02

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:25:57', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e78cf73-ce45-4660-822b-21dae65976ca'	System	12 Sep 2020 17:21:02
User entered 'No (N)'	System	12 Sep 2020 17:21:02

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:01', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e78cf73-ce45-4660-822b-21dae65976ca'	System	12 Sep 2020 17:21:02
User entered '12 Sep 2020 12:26'	System	12 Sep 2020 17:21:02

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 6'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:00:50', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4995c9d6-4248-4cbe-bb3f-c999209ad2cd'	System	13 Sep 2020 21:58:20
User entered 'Yes (Y)'	System	13 Sep 2020 21:58:20

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:08', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4995c9d6-4248-4cbe-bb3f-c999209ad2cd' User entered '97.5'	System	13 Sep 2020 21:58:20
	System	13 Sep 2020 21:58:20

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:13', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4995c9d6-4248-4cbe-bb3f-c999209ad2cd'	System	13 Sep 2020 21:58:20
User entered 'No (N)'	System	13 Sep 2020 21:58:20

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:20', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4995c9d6-4248-4cbe-bb3f-c999209ad2cd'	System	13 Sep 2020 21:58:20
User entered '13 Sep 2020 17:03'	System	13 Sep 2020 21:58:20

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 7'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:12', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9c7d18ff-a590-44c7-b842-245a5a6a9446'	System	08 Sep 2020 17:23:46
User entered 'None (1)'	System	08 Sep 2020 17:23:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:17', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9c7d18ff-a590-44c7-b842-245a5a6a9446'	System	08 Sep 2020 17:23:46
User entered 'No (N)'	System	08 Sep 2020 17:23:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:26', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9c7d18ff-a590-44c7-b842-245a5a6a9446'	System	08 Sep 2020 17:23:46
User entered 'No (N)'	System	08 Sep 2020 17:23:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:31', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9c7d18ff-a590-44c7-b842-245a5a6a9446'	System	08 Sep 2020 17:23:46
User entered 'None (1)'	System	08 Sep 2020 17:23:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:37', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9c7d18ff-a590-44c7-b842-245a5a6a9446'	System	08 Sep 2020 17:23:46
User entered '08 Sep 2020 12:28'	System	08 Sep 2020 17:23:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 14:30'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:37:06', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9bc7737e-8d81-4512-b708-f6fadd859976'	System	08 Sep 2020 21:32:49
User entered 'None (1)'	System	08 Sep 2020 21:32:49

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:37:24', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9bc7737e-8d81-4512-b708-f6fadd859976'	System	08 Sep 2020 21:32:49
User entered 'No (N)'	System	08 Sep 2020 21:32:49

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:37:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9bc7737e-8d81-4512-b708-f6fadd859976'	System	08 Sep 2020 21:32:49
User entered 'No (N)'	System	08 Sep 2020 21:32:49

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:37:40', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9bc7737e-8d81-4512-b708-f6fadd859976'	System	08 Sep 2020 21:32:49
User entered 'None (1)'	System	08 Sep 2020 21:32:49

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:37:44', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9bc7737e-8d81-4512-b708-f6fadd859976'	System	08 Sep 2020 21:32:49
User entered '08 Sep 2020 16:37'	System	08 Sep 2020 21:32:49

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 15:25'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 2'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:15', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '2750222c-fe42-49b5-8e3d-4a45e899eccb'	System	10 Sep 2020 14:44:37
User entered 'None (1)'	System	10 Sep 2020 14:44:37

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:20', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '2750222c-fe42-49b5-8e3d-4a45e899eccb'	System	10 Sep 2020 14:44:37
User entered 'No (N)'	System	10 Sep 2020 14:44:37

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:24', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '2750222c-fe42-49b5-8e3d-4a45e899eccb'	System	10 Sep 2020 14:44:37
User entered 'No (N)'	System	10 Sep 2020 14:44:37

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:29', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '2750222c-fe42-49b5-8e3d-4a45e899eccb'	System	10 Sep 2020 14:44:37
User entered 'None (1)'	System	10 Sep 2020 14:44:37

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:32', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '2750222c-fe42-49b5-8e3d-4a45e899eccb'	System	10 Sep 2020 14:44:37
User entered '10 Sep 2020 09:49'	System	10 Sep 2020 14:44:37

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 3'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:25', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9cccf5d0-6fc5-4145-bd8d-416f33158926'	System	10 Sep 2020 23:15:46
User entered 'None (1)'	System	10 Sep 2020 23:15:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:30', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9cccf5d0-6fc5-4145-bd8d-416f33158926'	System	10 Sep 2020 23:15:46
User entered 'No (N)'	System	10 Sep 2020 23:15:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:34', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9cccf5d0-6fc5-4145-bd8d-416f33158926'	System	10 Sep 2020 23:15:46
User entered 'No (N)'	System	10 Sep 2020 23:15:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9cccf5d0-6fc5-4145-bd8d-416f33158926'	System	10 Sep 2020 23:15:46
User entered 'None (1)'	System	10 Sep 2020 23:15:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:42', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9cccf5d0-6fc5-4145-bd8d-416f33158926'	System	10 Sep 2020 23:15:46
User entered '10 Sep 2020 18:20'	System	10 Sep 2020 23:15:46

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 4'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:22:44', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e199772-e43a-4119-b7b0-a35f88191e58'	System	11 Sep 2020 17:18:07
User entered 'None (1)'	System	11 Sep 2020 17:18:07

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:22:48', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e199772-e43a-4119-b7b0-a35f88191e58'	System	11 Sep 2020 17:18:07
User entered 'No (N)'	System	11 Sep 2020 17:18:07

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:22:52', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e199772-e43a-4119-b7b0-a35f88191e58'	System	11 Sep 2020 17:18:07
User entered 'No (N)'	System	11 Sep 2020 17:18:07

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:22:57', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e199772-e43a-4119-b7b0-a35f88191e58'	System	11 Sep 2020 17:18:07
User entered 'None (1)'	System	11 Sep 2020 17:18:07

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:02', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9e199772-e43a-4119-b7b0-a35f88191e58'	System	11 Sep 2020 17:18:07
User entered '11 Sep 2020 12:23'	System	11 Sep 2020 17:18:07

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 5'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:08', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '864b5d79-e14f-45b9-a9a8-974d24b9aaa8'	System	12 Sep 2020 17:21:25
User entered 'None (1)'	System	12 Sep 2020 17:21:25

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:13', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '864b5d79-e14f-45b9-a9a8-974d24b9aaa8'	System	12 Sep 2020 17:21:25
User entered 'No (N)'	System	12 Sep 2020 17:21:25

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:16', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '864b5d79-e14f-45b9-a9a8-974d24b9aaa8'	System	12 Sep 2020 17:21:25
User entered 'No (N)'	System	12 Sep 2020 17:21:25

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:20', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '864b5d79-e14f-45b9-a9a8-974d24b9aaa8'	System	12 Sep 2020 17:21:25
User entered 'None (1)'	System	12 Sep 2020 17:21:25

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:23', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '864b5d79-e14f-45b9-a9a8-974d24b9aaa8'	System	12 Sep 2020 17:21:25
User entered '12 Sep 2020 12:26'	System	12 Sep 2020 17:21:25

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 6'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:26', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e4fb9e2d-15e3-4019-9f4e-73e9804e5fd6'	System	13 Sep 2020 21:58:42
User entered 'None (1)'	System	13 Sep 2020 21:58:42

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:29', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e4fb9e2d-15e3-4019-9f4e-73e9804e5fd6'	System	13 Sep 2020 21:58:42
User entered 'No (N)'	System	13 Sep 2020 21:58:42

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e4fb9e2d-15e3-4019-9f4e-73e9804e5fd6'	System	13 Sep 2020 21:58:42
User entered 'No (N)'	System	13 Sep 2020 21:58:42

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:36', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e4fb9e2d-15e3-4019-9f4e-73e9804e5fd6'	System	13 Sep 2020 21:58:42
User entered 'None (1)'	System	13 Sep 2020 21:58:42

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:41', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e4fb9e2d-15e3-4019-9f4e-73e9804e5fd6'	System	13 Sep 2020 21:58:42
User entered '13 Sep 2020 17:03'	System	13 Sep 2020 21:58:42

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 7'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:45', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b4284266-ff99-4a1b-bc56-42c89f67a368'	System	08 Sep 2020 17:24:19
User entered 'None (0)'	System	08 Sep 2020 17:24:19

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:49', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b4284266-ff99-4a1b-bc56-42c89f67a368'	System	08 Sep 2020 17:24:19
User entered 'None (0)'	System	08 Sep 2020 17:24:19

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:52', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b4284266-ff99-4a1b-bc56-42c89f67a368'	System	08 Sep 2020 17:24:19
User entered 'None (0)'	System	08 Sep 2020 17:24:19

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:55', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b4284266-ff99-4a1b-bc56-42c89f67a368'	System	08 Sep 2020 17:24:19
User entered 'None (0)'	System	08 Sep 2020 17:24:19

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:28:59', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b4284266-ff99-4a1b-bc56-42c89f67a368'	System	08 Sep 2020 17:24:19
User entered 'None (0)'	System	08 Sep 2020 17:24:19

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:29:02', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b4284266-ff99-4a1b-bc56-42c89f67a368'	System	08 Sep 2020 17:24:19
User entered 'None (0)'	System	08 Sep 2020 17:24:19

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:29:07', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b4284266-ff99-4a1b-bc56-42c89f67a368'	System	08 Sep 2020 17:24:19
User entered 'No (N)'	System	08 Sep 2020 17:24:19

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T12:29:12', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b4284266-ff99-4a1b-bc56-42c89f67a368'	System	08 Sep 2020 17:24:19
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 17:24:19

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 14:30'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:37:50', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a4759431-c97c-49f1-bdbd-b76b4cae70de'	System	08 Sep 2020 21:33:21
User entered 'None (0)'	System	08 Sep 2020 21:33:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:37:54', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a4759431-c97c-49f1-bdbd-b76b4cae70de'	System	08 Sep 2020 21:33:21
User entered 'None (0)'	System	08 Sep 2020 21:33:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:37:57', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a4759431-c97c-49f1-bdbd-b76b4cae70de'	System	08 Sep 2020 21:33:21
User entered 'None (0)'	System	08 Sep 2020 21:33:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:38:01', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a4759431-c97c-49f1-bdbd-b76b4cae70de'	System	08 Sep 2020 21:33:21
User entered 'None (0)'	System	08 Sep 2020 21:33:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:38:04', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a4759431-c97c-49f1-bdbd-b76b4cae70de'	System	08 Sep 2020 21:33:21
User entered 'None (0)'	System	08 Sep 2020 21:33:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:38:07', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a4759431-c97c-49f1-bdbd-b76b4cae70de'	System	08 Sep 2020 21:33:21
User entered 'None (0)'	System	08 Sep 2020 21:33:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:38:11', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a4759431-c97c-49f1-bdbd-b76b4cae70de'	System	08 Sep 2020 21:33:21
User entered 'No (N)'	System	08 Sep 2020 21:33:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-08T16:38:16', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a4759431-c97c-49f1-bdbd-b76b4cae70de'	System	08 Sep 2020 21:33:21
User entered '08 Sep 2020 16:38'	System	08 Sep 2020 21:33:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '08 Sep 2020 15:25'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 2'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ae053226-d083-4a7b-be6e-d8f6499bf733'	System	10 Sep 2020 14:45:07
User entered 'None (0)'	System	10 Sep 2020 14:45:07

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:42', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ae053226-d083-4a7b-be6e-d8f6499bf733'	System	10 Sep 2020 14:45:07
User entered 'None (0)'	System	10 Sep 2020 14:45:07

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:45', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ae053226-d083-4a7b-be6e-d8f6499bf733'	System	10 Sep 2020 14:45:07
User entered 'None (0)'	System	10 Sep 2020 14:45:07

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:48', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ae053226-d083-4a7b-be6e-d8f6499bf733'	System	10 Sep 2020 14:45:07
User entered 'None (0)'	System	10 Sep 2020 14:45:07

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:51', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ae053226-d083-4a7b-be6e-d8f6499bf733'	System	10 Sep 2020 14:45:07
User entered 'None (0)'	System	10 Sep 2020 14:45:07

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:49:55', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ae053226-d083-4a7b-be6e-d8f6499bf733'	System	10 Sep 2020 14:45:07
User entered 'None (0)'	System	10 Sep 2020 14:45:07

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:50:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ae053226-d083-4a7b-be6e-d8f6499bf733'	System	10 Sep 2020 14:45:07
User entered 'No (N)'	System	10 Sep 2020 14:45:07

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T09:50:03', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ae053226-d083-4a7b-be6e-d8f6499bf733'	System	10 Sep 2020 14:45:07
User entered '10 Sep 2020 09:50'	System	10 Sep 2020 14:45:07

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 3'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:49', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b46f3f9-103f-4bba-a174-8bdeca59f13e'	System	10 Sep 2020 23:16:17
User entered 'None (0)'	System	10 Sep 2020 23:16:17

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:52', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b46f3f9-103f-4bba-a174-8bdeca59f13e'	System	10 Sep 2020 23:16:17
User entered 'None (0)'	System	10 Sep 2020 23:16:17

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:20:56', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b46f3f9-103f-4bba-a174-8bdeca59f13e'	System	10 Sep 2020 23:16:17
User entered 'None (0)'	System	10 Sep 2020 23:16:17

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:21:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b46f3f9-103f-4bba-a174-8bdeca59f13e'	System	10 Sep 2020 23:16:17
User entered 'None (0)'	System	10 Sep 2020 23:16:17

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:21:03', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b46f3f9-103f-4bba-a174-8bdeca59f13e'	System	10 Sep 2020 23:16:17
User entered 'None (0)'	System	10 Sep 2020 23:16:17

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:21:06', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b46f3f9-103f-4bba-a174-8bdeca59f13e'	System	10 Sep 2020 23:16:17
User entered 'None (0)'	System	10 Sep 2020 23:16:17

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:21:10', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b46f3f9-103f-4bba-a174-8bdeca59f13e'	System	10 Sep 2020 23:16:17
User entered 'No (N)'	System	10 Sep 2020 23:16:17

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-10T18:21:13', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b46f3f9-103f-4bba-a174-8bdeca59f13e'	System	10 Sep 2020 23:16:17
User entered '10 Sep 2020 18:21'	System	10 Sep 2020 23:16:17

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 4'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:09', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a30482f8-107a-49de-a3eb-079386592d0f'	System	11 Sep 2020 17:18:43
User entered 'None (0)'	System	11 Sep 2020 17:18:43

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:12', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a30482f8-107a-49de-a3eb-079386592d0f'	System	11 Sep 2020 17:18:43
User entered 'None (0)'	System	11 Sep 2020 17:18:43

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:16', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a30482f8-107a-49de-a3eb-079386592d0f'	System	11 Sep 2020 17:18:43
User entered 'None (0)'	System	11 Sep 2020 17:18:43

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:19', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a30482f8-107a-49de-a3eb-079386592d0f'	System	11 Sep 2020 17:18:43
User entered 'None (0)'	System	11 Sep 2020 17:18:43

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:22', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a30482f8-107a-49de-a3eb-079386592d0f'	System	11 Sep 2020 17:18:43
User entered 'None (0)'	System	11 Sep 2020 17:18:43

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:26', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a30482f8-107a-49de-a3eb-079386592d0f'	System	11 Sep 2020 17:18:43
User entered 'None (0)'	System	11 Sep 2020 17:18:43

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:29', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a30482f8-107a-49de-a3eb-079386592d0f'	System	11 Sep 2020 17:18:43
User entered 'No (N)'	System	11 Sep 2020 17:18:43

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-11T12:23:34', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'a30482f8-107a-49de-a3eb-079386592d0f'	System	11 Sep 2020 17:18:43
User entered '11 Sep 2020 12:23'	System	11 Sep 2020 17:18:43

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 5'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:29', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4533e686-36e1-4e7a-bd92-e706857bda01'	System	12 Sep 2020 17:21:54
User entered 'None (0)'	System	12 Sep 2020 17:21:54

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4533e686-36e1-4e7a-bd92-e706857bda01'	System	12 Sep 2020 17:21:54
User entered 'None (0)'	System	12 Sep 2020 17:21:54

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4533e686-36e1-4e7a-bd92-e706857bda01'	System	12 Sep 2020 17:21:54
User entered 'None (0)'	System	12 Sep 2020 17:21:54

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:40', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4533e686-36e1-4e7a-bd92-e706857bda01'	System	12 Sep 2020 17:21:54
User entered 'None (0)'	System	12 Sep 2020 17:21:54

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:43', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4533e686-36e1-4e7a-bd92-e706857bda01'	System	12 Sep 2020 17:21:54
User entered 'None (0)'	System	12 Sep 2020 17:21:54

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:46', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4533e686-36e1-4e7a-bd92-e706857bda01'	System	12 Sep 2020 17:21:54
User entered 'None (0)'	System	12 Sep 2020 17:21:54

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:49', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4533e686-36e1-4e7a-bd92-e706857bda01'	System	12 Sep 2020 17:21:54
User entered 'No (N)'	System	12 Sep 2020 17:21:54

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-12T12:26:53', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4533e686-36e1-4e7a-bd92-e706857bda01'	System	12 Sep 2020 17:21:54
User entered '12 Sep 2020 12:26'	System	12 Sep 2020 17:21:54

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 6'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:45', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e1878d62-a6ef-4960-b777-82bca84f279b'	System	13 Sep 2020 21:59:09
User entered 'None (0)'	System	13 Sep 2020 21:59:09

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:48', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e1878d62-a6ef-4960-b777-82bca84f279b'	System	13 Sep 2020 21:59:09
User entered 'None (0)'	System	13 Sep 2020 21:59:09

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:51', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e1878d62-a6ef-4960-b777-82bca84f279b'	System	13 Sep 2020 21:59:09
User entered 'None (0)'	System	13 Sep 2020 21:59:09

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:55', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e1878d62-a6ef-4960-b777-82bca84f279b'	System	13 Sep 2020 21:59:09
User entered 'None (0)'	System	13 Sep 2020 21:59:09

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:03:58', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e1878d62-a6ef-4960-b777-82bca84f279b'	System	13 Sep 2020 21:59:09
User entered 'None (0)'	System	13 Sep 2020 21:59:09

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:04:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e1878d62-a6ef-4960-b777-82bca84f279b'	System	13 Sep 2020 21:59:09
User entered 'None (0)'	System	13 Sep 2020 21:59:09

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:04:04', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e1878d62-a6ef-4960-b777-82bca84f279b'	System	13 Sep 2020 21:59:09
User entered 'No (N)'	System	13 Sep 2020 21:59:09

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-09-13T17:04:07', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e1878d62-a6ef-4960-b777-82bca84f279b'	System	13 Sep 2020 21:59:09
User entered '13 Sep 2020 17:04'	System	13 Sep 2020 21:59:09

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	08 Sep 2020 17:21:24
User entered 'Day 7'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

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 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:21:24

US3342023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:21:24

US3342023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	15 Sep 2020 20:22:01

US3342023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '15 Sep 2020'	Ethan Shotton (b) (4)	15 Sep 2020 20:22:01

US3342023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	15 Sep 2020 20:22:01

US3342023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Ethan Shotton (b) (4)	15 Sep 2020 20:22:01

US3342023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	15 Sep 2020 20:22:05

US3342023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'I'	System	15 Sep 2020 20:22:05

US3342023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	22 Sep 2020 20:34:14

US3342023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '22 Sep 2020'	Ethan Shotton (b) (4)	22 Sep 2020 20:34:14

US3342023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	22 Sep 2020 20:34:14

US3342023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Ethan Shotton (b) (4)	22 Sep 2020 20:34:14

US3342023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	22 Sep 2020 20:34:18

US3342023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'I'	System	22 Sep 2020 20:34:18

US3342023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	30 Sep 2020 14:38:36

US3342023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '30 Sep 2020'	Ethan Shotton (b) (4)	30 Sep 2020 14:38:36

US3342023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	30 Sep 2020 14:38:36

US3342023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 14:38:36

US3342023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	30 Sep 2020 14:38:40

US3342023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'I'	System	30 Sep 2020 14:38:40

US3342023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Andrew Bell (b) (4)	06 Oct 2020 16:05:11

US3342023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '6 Oct 2020'	Andrew Bell (b) (4)	06 Oct 2020 16:05:11

US3342023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Clinic (Clinic)'	Andrew Bell (b) (4)	06 Oct 2020 16:05:11

US3342023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'VISIT3'	System	06 Oct 2020 16:05:11

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '6 Oct 2020'	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '10:44'	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '6 Oct 2020 10:44'	System	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '98.1' F	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Oral (Oral)'	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '73'	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'bpm'	System	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '12'	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'breaths/min'	System	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '129'	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '81'	Andrew Bell (b) (4)	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'mmHg'	System	06 Oct 2020 16:05:52

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39

US3342023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39

US3342023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'No (N)'	Andrew Bell (b) (4)	06 Oct 2020 16:05:57

US3342023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered empty.	Andrew Bell (b) (4)	06 Oct 2020 16:05:57

US3342023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Andrew Bell (b) (4)	06 Oct 2020 16:10:41

US3342023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '6 Oct 2020'	Andrew Bell (b) (4)	06 Oct 2020 16:10:41

US3342023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered '11:08'	Andrew Bell (b) (4)	06 Oct 2020 16:10:41

US3342023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '6 Oct 2020 11:08'	System	06 Oct 2020 16:10:41

US3342023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:20:54
User entered 'Yes (Y)'	Andrew Bell (b) (4)	06 Oct 2020 16:10:46

US3342023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered '1'	System	06 Oct 2020 16:10:46

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 64'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-11T00:02:03', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '73747d99-f8a8-4be5-9e83-ca2be3cbf4e1'	System	11 Oct 2020 05:03:04
User entered 'No (N)'	System	11 Oct 2020 05:03:04

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-11T00:02:09', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '73747d99-f8a8-4be5-9e83-ca2be3cbf4e1'	System	11 Oct 2020 05:03:04
User entered 'No (N)'	System	11 Oct 2020 05:03:04

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-11T00:02:19', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '73747d99-f8a8-4be5-9e83-ca2be3cbf4e1' User entered '11 Oct 2020 00:02:19'	System	11 Oct 2020 05:03:04
	System	11 Oct 2020 05:03:04

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 71'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-19T06:56:57', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cd5a7f75-22f0-41f4-be2e-f846ddb6013b'	System	19 Oct 2020 11:57:51
User entered 'No (N)'	System	19 Oct 2020 11:57:51

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-19T06:57:06', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cd5a7f75-22f0-41f4-be2e-f846ddb6013b'	System	19 Oct 2020 11:57:51
User entered 'No (N)'	System	19 Oct 2020 11:57:51

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-19T06:57:15', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'cd5a7f75-22f0-41f4-be2e-f846ddb6013b'	System	19 Oct 2020 11:57:51
User entered '19 Oct 2020 06:57:15'	System	19 Oct 2020 11:57:51

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 78'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-26T15:38:55', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f83e7d64-3cac-4148-a6bf-75f41923d731'	System	26 Oct 2020 20:39:36
User entered 'No (N)'	System	26 Oct 2020 20:39:36

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-26T15:39:02', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f83e7d64-3cac-4148-a6bf-75f41923d731'	System	26 Oct 2020 20:39:36
User entered 'No (N)'	System	26 Oct 2020 20:39:36

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-10-26T15:39:09', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f83e7d64-3cac-4148-a6bf-75f41923d731' User entered '26 Oct 2020 15:39:09'	System	26 Oct 2020 20:39:36
	System	26 Oct 2020 20:39:36

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 92'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-11-10T13:37:04', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f140c45b-47b9-4196-b19a-5d17317b69e8'	System	10 Nov 2020 19:37:29
User entered 'No (N)'	System	10 Nov 2020 19:37:29

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-11-10T13:37:09', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f140c45b-47b9-4196-b19a-5d17317b69e8'	System	10 Nov 2020 19:37:29
User entered 'No (N)'	System	10 Nov 2020 19:37:29

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-11-10T13:37:14', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f140c45b-47b9-4196-b19a-5d17317b69e8'	System	10 Nov 2020 19:37:29
User entered '10 Nov 2020 13:37:14'	System	10 Nov 2020 19:37:29

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered 'Day 99'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-11-16T20:57:21', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '2c3192a6-85e1-4134-9067-648efe0d4d37'	System	17 Nov 2020 02:57:40
User entered 'No (N)'	System	17 Nov 2020 02:57:40

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-11-16T20:57:28', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '2c3192a6-85e1-4134-9067-648efe0d4d37'	System	17 Nov 2020 02:57:40
User entered 'No (N)'	System	17 Nov 2020 02:57:40

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-11-16T20:57:34', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '2c3192a6-85e1-4134-9067-648efe0d4d37'	System	17 Nov 2020 02:57:40
User entered '16 Nov 2020 20:57:34'	System	17 Nov 2020 02:57:40

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 18:26:08

US3342023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:21:21
Data entry locked.	System	11 Aug 2020 18:26:08
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 18:26:08

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2020-11-23T12:54:42', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '3f9cdb08-8c41-4b08-8053-a3e50b1197c8'	System	23 Nov 2020 18:54:52
User entered 'No (N)'	System	23 Nov 2020 18:54:52

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2020-11-23T12:54:47', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '3f9cdb08-8c41-4b08-8053-a3e50b1197c8'	System	23 Nov 2020 18:54:52
User entered 'No (N)'	System	23 Nov 2020 18:54:52

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-11-23T12:54:55', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '3f9cdb08-8c41-4b08-8053-a3e50b1197c8'	System	23 Nov 2020 18:54:52
User entered '23 Nov 2020 12:54:55'	System	23 Nov 2020 18:54:52

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2020-11-30T06:47:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b7a8fa7f-84b9-4837-a195-deb8ba81e865'	System	30 Nov 2020 12:47:43
User entered 'No (N)'	System	30 Nov 2020 12:47:43

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2020-11-30T06:47:40', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b7a8fa7f-84b9-4837-a195-deb8ba81e865'	System	30 Nov 2020 12:47:43
User entered 'No (N)'	System	30 Nov 2020 12:47:43

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-11-30T06:47:48', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b7a8fa7f-84b9-4837-a195-deb8ba81e865'	System	30 Nov 2020 12:47:43
User entered '30 Nov 2020 06:47:48'	System	30 Nov 2020 12:47:43

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2020-12-07T08:28:02', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ca3746d1-5b64-438d-978c-fd2510a05714'	System	07 Dec 2020 14:27:56
User entered 'No (N)'	System	07 Dec 2020 14:27:56

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2020-12-07T08:28:07', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ca3746d1-5b64-438d-978c-fd2510a05714'	System	07 Dec 2020 14:27:56
User entered 'No (N)'	System	07 Dec 2020 14:27:56

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-12-07T08:28:14', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'ca3746d1-5b64-438d-978c-fd2510a05714'	System	07 Dec 2020 14:27:56
User entered '07 Dec 2020 08:28:14'	System	07 Dec 2020 14:27:56

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2020-12-14T09:26:25', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '8d1178a3-8ba4-430b-bdc7-4137c0578f0a'	System	14 Dec 2020 15:26:13
User entered 'No (N)'	System	14 Dec 2020 15:26:13

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2020-12-14T09:26:28', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '8d1178a3-8ba4-430b-bdc7-4137c0578f0a'	System	14 Dec 2020 15:26:13
User entered 'No (N)'	System	14 Dec 2020 15:26:13

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-12-14T09:26:35', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '8d1178a3-8ba4-430b-bdc7-4137c0578f0a'	System	14 Dec 2020 15:26:13
User entered '14 Dec 2020 09:26:35'	System	14 Dec 2020 15:26:13

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2020-12-21T09:55:39', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bba358b6-47c6-4ffd-8ff5-d435d7df86b0'	System	21 Dec 2020 15:55:17
User entered 'No (N)'	System	21 Dec 2020 15:55:17

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2020-12-21T09:55:43', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bba358b6-47c6-4ffd-8ff5-d435d7df86b0'	System	21 Dec 2020 15:55:17
User entered 'No (N)'	System	21 Dec 2020 15:55:17

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-12-21T09:55:50', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'bba358b6-47c6-4ffd-8ff5-d435d7df86b0'	System	21 Dec 2020 15:55:17
User entered '21 Dec 2020 09:55:50'	System	21 Dec 2020 15:55:17

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2020-12-24T00:01:39', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4b8464b5-08e2-4a0b-8484-dc10bcf691d3'	System	24 Dec 2020 06:01:22
User entered 'No (N)'	System	24 Dec 2020 06:01:22

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2020-12-24T00:01:44', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4b8464b5-08e2-4a0b-8484-dc10bcf691d3'	System	24 Dec 2020 06:01:22
User entered 'No (N)'	System	24 Dec 2020 06:01:22

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-12-24T00:01:53', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '4b8464b5-08e2-4a0b-8484-dc10bcf691d3'	System	24 Dec 2020 06:01:22
User entered '24 Dec 2020 00:01:53'	System	24 Dec 2020 06:01:22

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2020-12-31T02:26:37', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9e0e134-1895-4456-9bf7-53de4c0d1773'	System	31 Dec 2020 08:26:05
User entered 'No (N)'	System	31 Dec 2020 08:26:05

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2020-12-31T02:26:42', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9e0e134-1895-4456-9bf7-53de4c0d1773'	System	31 Dec 2020 08:26:05
User entered 'No (N)'	System	31 Dec 2020 08:26:05

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2020-12-31T02:26:46', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f9e0e134-1895-4456-9bf7-53de4c0d1773'	System	31 Dec 2020 08:26:05
User entered '31 Dec 2020 02:26:46'	System	31 Dec 2020 08:26:05

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-01-07T21:55:05', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7bf737af-e92e-401d-b017-637ce42b5507'	System	08 Jan 2021 03:54:35
User entered 'No (N)'	System	08 Jan 2021 03:54:35

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-01-07T21:55:17', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7bf737af-e92e-401d-b017-637ce42b5507'	System	08 Jan 2021 03:54:35
User entered 'No (N)'	System	08 Jan 2021 03:54:35

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-01-07T21:55:24', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7bf737af-e92e-401d-b017-637ce42b5507'	System	08 Jan 2021 03:54:35
User entered '07 Jan 2021 21:55:24'	System	08 Jan 2021 03:54:35

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-01-14T08:49:56', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b779c8af-f84a-4323-a794-5205f332dc80'	System	14 Jan 2021 14:49:09
User entered 'No (N)'	System	14 Jan 2021 14:49:09

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-01-14T08:50:01', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b779c8af-f84a-4323-a794-5205f332dc80'	System	14 Jan 2021 14:49:09
User entered 'No (N)'	System	14 Jan 2021 14:49:09

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-01-14T08:50:06', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'b779c8af-f84a-4323-a794-5205f332dc80'	System	14 Jan 2021 14:49:09
User entered '14 Jan 2021 08:50:06'	System	14 Jan 2021 14:49:09

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-01-21T08:05:45', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '650ac2c9-087a-4034-881d-40b2e109ba44'	System	21 Jan 2021 14:04:49
User entered 'No (N)'	System	21 Jan 2021 14:04:49

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-01-21T08:05:50', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '650ac2c9-087a-4034-881d-40b2e109ba44'	System	21 Jan 2021 14:04:49
User entered 'No (N)'	System	21 Jan 2021 14:04:49

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-01-21T08:05:54', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '650ac2c9-087a-4034-881d-40b2e109ba44'	System	21 Jan 2021 14:04:49
User entered '21 Jan 2021 08:05:54'	System	21 Jan 2021 14:04:49

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-01-28T08:59:32', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f5f04650-a137-451b-9615-608d70deb4bf'	System	28 Jan 2021 14:58:28
User entered 'No (N)'	System	28 Jan 2021 14:58:28

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-01-28T08:59:36', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f5f04650-a137-451b-9615-608d70deb4bf'	System	28 Jan 2021 14:58:28
User entered 'No (N)'	System	28 Jan 2021 14:58:28

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-01-28T08:59:41', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'f5f04650-a137-451b-9615-608d70deb4bf'	System	28 Jan 2021 14:58:28
User entered '28 Jan 2021 08:59:41'	System	28 Jan 2021 14:58:28

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-02-04T04:14:06', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9a1a93fc-fc19-4b65-b74e-d02c06c53fbd'	System	04 Feb 2021 10:13:31
User entered 'No (N)'	System	04 Feb 2021 10:13:31

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-02-04T04:14:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9a1a93fc-fc19-4b65-b74e-d02c06c53fbd'	System	04 Feb 2021 10:13:31
User entered 'No (N)'	System	04 Feb 2021 10:13:31

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-02-04T04:14:52', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9a1a93fc-fc19-4b65-b74e-d02c06c53fbd' User entered '04 Feb 2021 04:14:52'	System	04 Feb 2021 10:13:31
	System	04 Feb 2021 10:13:31

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-02-11T15:06:23', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9387c24c-9187-4c16-abbe-258ecf7410fe'	System	11 Feb 2021 21:05:07
User entered 'No (N)'	System	11 Feb 2021 21:05:07

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-02-11T15:06:27', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9387c24c-9187-4c16-abbe-258ecf7410fe'	System	11 Feb 2021 21:05:07
User entered 'No (N)'	System	11 Feb 2021 21:05:07

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-02-11T15:06:33', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '9387c24c-9187-4c16-abbe-258ecf7410fe'	System	11 Feb 2021 21:05:07
User entered '11 Feb 2021 15:06:33'	System	11 Feb 2021 21:05:07

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-02-19T16:53:27', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b4e548b-5f4a-43a7-b9bf-a9fc8a200e7f'	System	19 Feb 2021 22:52:01
User entered 'No (N)'	System	19 Feb 2021 22:52:01

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-02-19T16:53:31', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b4e548b-5f4a-43a7-b9bf-a9fc8a200e7f'	System	19 Feb 2021 22:52:01
User entered 'No (N)'	System	19 Feb 2021 22:52:01

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-02-19T16:53:38', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '6b4e548b-5f4a-43a7-b9bf-a9fc8a200e7f'	System	19 Feb 2021 22:52:01
User entered '19 Feb 2021 16:53:38'	System	19 Feb 2021 22:52:01

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-02-25T09:33:58-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '8ee70941-9bed-4734-afa8-87cff4c4b06c'	System	25 Feb 2021 16:51:35
User entered 'No (N)'	System	25 Feb 2021 16:51:35

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-02-25T09:34:03-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '8ee70941-9bed-4734-afa8-87cff4c4b06c'	System	25 Feb 2021 16:51:35
User entered 'No (N)'	System	25 Feb 2021 16:51:35

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-02-25T09:34:10-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '8ee70941-9bed-4734-afa8-87cff4c4b06c'	System	25 Feb 2021 16:51:35
User entered '25 Feb 2021 09:34:10'	System	25 Feb 2021 16:51:35

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-03-04T10:15:23-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7da8c73e-c476-4928-9e1f-646989ba7a9c'	System	04 Mar 2021 16:13:49
User entered 'No (N)'	System	04 Mar 2021 16:13:49

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-03-04T10:15:30-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7da8c73e-c476-4928-9e1f-646989ba7a9c'	System	04 Mar 2021 16:13:49
User entered 'No (N)'	System	04 Mar 2021 16:13:49

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-03-04T10:15:35-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7da8c73e-c476-4928-9e1f-646989ba7a9c' User entered '04 Mar 2021 10:15:35'	System	04 Mar 2021 16:13:49
	System	04 Mar 2021 16:13:49

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-03-11T07:45:15-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e5bce72f-ef0b-4ea2-8945-cd566ff0c4d8'	System	11 Mar 2021 13:43:24
User entered 'No (N)'	System	11 Mar 2021 13:43:24

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-03-11T07:45:19-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e5bce72f-ef0b-4ea2-8945-cd566ff0c4d8'	System	11 Mar 2021 13:43:24
User entered 'No (N)'	System	11 Mar 2021 13:43:24

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-03-11T07:45:23-06:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'e5bce72f-ef0b-4ea2-8945-cd566ff0c4d8'	System	11 Mar 2021 13:43:24
User entered '11 Mar 2021 07:45:23'	System	11 Mar 2021 13:43:24

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-03-18T10:23:15-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '540394c4-51cc-4b3d-b7cd-27347b22180e'	System	18 Mar 2021 15:21:17
User entered 'No (N)'	System	18 Mar 2021 15:21:17

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-03-18T10:23:19-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '540394c4-51cc-4b3d-b7cd-27347b22180e'	System	18 Mar 2021 15:21:17
User entered 'No (N)'	System	18 Mar 2021 15:21:17

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-03-18T10:23:24-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '540394c4-51cc-4b3d-b7cd-27347b22180e' User entered '18 Mar 2021 10:23:24'	System	18 Mar 2021 15:21:17
	System	18 Mar 2021 15:21:17

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-03-25T07:16:18-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '3240ea75-4286-44c1-8386-a2ea6dc8fc34'	System	25 Mar 2021 12:14:19
User entered 'No (N)'	System	25 Mar 2021 12:14:19

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-03-25T07:16:25-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '3240ea75-4286-44c1-8386-a2ea6dc8fc34'	System	25 Mar 2021 12:14:19
User entered 'No (N)'	System	25 Mar 2021 12:14:19

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-03-25T07:16:31-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '3240ea75-4286-44c1-8386-a2ea6dc8fc34' User entered '25 Mar 2021 07:16:31'	System	25 Mar 2021 12:14:19
	System	25 Mar 2021 12:14:19

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-04-01T03:36:30-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c6293a5d-6dcf-41df-883e-d76586b2be2c' User entered 'No (N)'	System	01 Apr 2021 08:34:19
	System	01 Apr 2021 08:34:19

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-04-01T03:36:34-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c6293a5d-6dcf-41df-883e-d76586b2be2c'	System	01 Apr 2021 08:34:19
User entered 'No (N)'	System	01 Apr 2021 08:34:19

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-04-01T03:36:40-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c6293a5d-6dcf-41df-883e-d76586b2be2c'	System	01 Apr 2021 08:34:19
User entered '01 Apr 2021 03:36:40'	System	01 Apr 2021 08:34:19

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-04-08T00:08:54-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '491e2c5f-3476-4ed4-9696-0fa4dcf458ad' User entered 'Yes (Y)'	System	08 Apr 2021 05:07:08
	System	08 Apr 2021 05:07:08

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-04-08T00:09:01-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '491e2c5f-3476-4ed4-9696-0fa4dcf458ad'	System	08 Apr 2021 05:07:08
User entered 'No (N)'	System	08 Apr 2021 05:07:08

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-04-08T00:09:11-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '491e2c5f-3476-4ed4-9696-0fa4dcf458ad' User entered 'No (N)'	System	08 Apr 2021 05:07:08
	System	08 Apr 2021 05:07:08

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-04-08T00:09:23-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '491e2c5f-3476-4ed4-9696-0fa4dcf458ad' User entered 'No (N)'	System	08 Apr 2021 05:07:08

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-04-08T00:09:36-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '491e2c5f-3476-4ed4-9696-0fa4dcf458ad' User entered '08 Apr 2021 00:09:36'	System	08 Apr 2021 05:07:08
	System	08 Apr 2021 05:07:08

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-04-15T14:21:21-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '63734688-2e84-41e3-9dbd-3ce585600f3e' User entered 'No (N)'	System	15 Apr 2021 19:18:54
	System	15 Apr 2021 19:18:54

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-04-15T14:21:25-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '63734688-2e84-41e3-9dbd-3ce585600f3e' User entered 'No (N)'	System	15 Apr 2021 19:18:54
	System	15 Apr 2021 19:18:54

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-04-15T14:21:29-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '63734688-2e84-41e3-9dbd-3ce585600f3e'	System	15 Apr 2021 19:18:54
User entered '15 Apr 2021 14:21:29'	System	15 Apr 2021 19:18:54

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-04-22T08:40:09-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c87e6590-0b7a-4245-92f8-cc4561f96c9c'	System	22 Apr 2021 13:37:39
User entered 'No (N)'	System	22 Apr 2021 13:37:39

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-04-22T08:40:13-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c87e6590-0b7a-4245-92f8-cc4561f96c9c'	System	22 Apr 2021 13:37:39
User entered 'No (N)'	System	22 Apr 2021 13:37:39

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-04-22T08:40:22-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: 'c87e6590-0b7a-4245-92f8-cc4561f96c9c'	System	22 Apr 2021 13:37:39
User entered '22 Apr 2021 08:40:22'	System	22 Apr 2021 13:37:39

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[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 (a91203375cd0dda5)', Time: '2021-04-29T07:22:32-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7c4d43a7-08bc-4ad4-86e0-be9643fe6e5d' User entered 'No (N)'	System	29 Apr 2021 12:19:54
	System	29 Apr 2021 12:19:54

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

Have you been exposed to someone with 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 (a91203375cd0dda5)', Time: '2021-04-29T07:22:36-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7c4d43a7-08bc-4ad4-86e0-be9643fe6e5d'	System	29 Apr 2021 12:19:54
User entered 'No (N)'	System	29 Apr 2021 12:19:54

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a91203375cd0dda5)', Time: '2021-04-29T07:22:44-05:00', User OID: 'PatientReportedOutcome (US3342023)', ODM File OID: '7c4d43a7-08bc-4ad4-86e0-be9643fe6e5d' User entered '29 Apr 2021 07:22:44'	System	29 Apr 2021 12:19:54
	System	29 Apr 2021 12:19:54

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:55:10

US3342023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:10
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:55:10

US3342023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	02 Nov 2020 21:35:56

US3342023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered '2 Nov 2020'	Ethan Shotton (b) (4)	02 Nov 2020 21:35:56

US3342023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	02 Nov 2020 21:35:56

US3342023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered empty.	Ethan Shotton (b) (4)	02 Nov 2020 21:35:56

US3342023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	02 Nov 2020 21:36:00

US3342023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:11:39
User entered 'I'	System	02 Nov 2020 21:36:00

US3342023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:36:56

US3342023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:36:56

US3342023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:36:56

US3342023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:36:56

US3342023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:37:01

US3342023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User entered 'I'	System	06 Jan 2021 15:37:01

US3342023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:37:16

US3342023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:37:16

US3342023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:37:16

US3342023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:37:16

US3342023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:37:22

US3342023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User entered 'I'	System	06 Jan 2021 15:37:22

US3342023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:44:55

US3342023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:44:55

US3342023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:44:55

US3342023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:44:55

US3342023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:44:45

US3342023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:56:57
User entered '1'	System	03 Feb 2021 20:44:45

US3342023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:25:27

US3342023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:25:27

US3342023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[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 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:25:27

US3342023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User entered 'VISIT4'	System	30 Mar 2021 19:25:27

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	30 Mar 2021 19:32:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:32:26
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	30 Mar 2021 19:32:22
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '10:24'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User entered '10 Mar 2021 10:24'	System	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '76'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User entered 'bpm'	System	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '12'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User entered 'breaths/min'	System	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '119'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User entered 'mmHg'	System	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '76'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User entered 'mmHg'	System	30 Mar 2021 19:32:22

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03

US3342023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03

US3342023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:25:34

US3342023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:25:34

US3342023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:33:11

US3342023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:33:11

US3342023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '10:47'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:33:11

US3342023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User entered '10 Mar 2021 10:47'	System	30 Mar 2021 19:33:11

US3342023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:33:30

US3342023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:24:03
User entered 'I'	System	30 Mar 2021 19:33:30

US3342023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:33:36

US3342023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:33:36

US3342023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:33:36

US3342023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:33:36

US3342023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:33:41

US3342023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 16:33:41

US3342023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	03 May 2021 22:42:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:37:41

US3342023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	03 May 2021 22:42:14
User entered '03 May 2021'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:37:41

US3342023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	03 May 2021 22:42:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:37:41

US3342023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	03 May 2021 22:42:14
User entered empty.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:37:41

US3342023

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	03 May 2021 22:42:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 May 2021 16:37:47

US3342023

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 16:37:47

US3342023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:27:06

US3342023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '5 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:27:06

US3342023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Clinic (Clinic)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:27:06

US3342023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 17:27:06

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '5 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:27:23

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '0'	Ethan Shotton (b) (4)	09 Mar 2021 02:17:25
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:34:44

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:27:23

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	Ethan Shotton (b) (4)	09 Mar 2021 02:17:25
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:34:44

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '5 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:27:23

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Placebo (Placebo)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:27:23

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:40:26
User entered 'Placebo (Placebo)'	Stefanie Mott (b) (4)	05 Jan 2021 17:27:23

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:40:26
User entered 'Placebo (Placebo)'	Stefanie Mott (b) (4)	05 Jan 2021 17:27:23

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:27:23

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered '1'	System	05 Jan 2021 17:27:23

US3342023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'I'	System	05 Jan 2021 17:27:23

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '163.0' cm	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '88.5' kg	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered '33.30950'	System	05 Jan 2021 17:28:10
DataPoint set to visible.	System	05 Jan 2021 17:27:23

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '163.0' cm	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '88.5' kg	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered '33.30950'	System	05 Jan 2021 17:28:10
DataPoint set to visible.	System	05 Jan 2021 17:27:23

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User accepted default value 'Pre-Dose (PREDOSE)'	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '5 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '10:48'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered '5 Jan 2021 10:48'	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '98.1' F	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Oral (Oral)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '75'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'bpm'	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '16'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'breaths/min'	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '142'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'mmHg'	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '77'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'mmHg'	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '163.0' cm	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '88.5' kg	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered '33.30950'	System	05 Jan 2021 17:28:10
DataPoint set to visible.	System	05 Jan 2021 17:27:23

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User accepted default value 'Post-Dose (POSTDOSE)'	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
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	05 Jan 2021 18:08:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:28:10
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '5 Jan 2021' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '11:59' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered '5 Jan 2021 11:59'	System	05 Jan 2021 18:08:31
User entered empty.	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '97.7' F reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '73' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'bpm'	System	05 Jan 2021 18:08:31
User entered empty.	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '16' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'breaths/min'	System	05 Jan 2021 18:08:31
User entered empty.	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '126' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'mmHg'	System	05 Jan 2021 18:08:31
User entered empty.	System	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '83' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 18:08:31
User entered empty.	Stefanie Mott (b) (4)	05 Jan 2021 17:28:10

US3342023

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'mmHg'	System	05 Jan 2021 18:08:31
User entered empty.	System	05 Jan 2021 17:28:10

US3342023

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:19

US3342023

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '5 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:28:19

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:46:32

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:46:32

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

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)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:46:32

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'mRNA-1273'	System	05 Jan 2021 17:46:32
DataPoint set to visible.	System	05 Jan 2021 17:27:23

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '5 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:46:32

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '11:29'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:46:32

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '5 Jan 2021 11:29'	System	05 Jan 2021 17:46:32

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:46:32

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'ONCE'	System	05 Jan 2021 17:46:32

US3342023

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

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 17:46:32

US3342023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	12 Jan 2021 22:34:28

US3342023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '05 Jan 2021'	Eileen Euperio (b) (4)	12 Jan 2021 22:34:28

US3342023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '11:20'	Eileen Euperio (b) (4)	12 Jan 2021 22:34:28

US3342023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '05 Jan 2021 11:20'	System	12 Jan 2021 22:34:28

US3342023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	12 Jan 2021 22:34:17

US3342023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '05 Jan 2021'	Eileen Euperio (b) (4)	12 Jan 2021 22:34:17

US3342023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '11:22'	Eileen Euperio (b) (4)	12 Jan 2021 22:34:17

US3342023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:01

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '05 Jan 2021 11:22'	System	12 Jan 2021 22:34:17

US3342023

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

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:46:58

US3342023

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

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '1'	System	05 Jan 2021 17:46:58

US3342023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	14 Jan 2021 17:57:05

US3342023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered '14 Jan 2021'	Ethan Shotton (b) (4)	14 Jan 2021 17:57:05

US3342023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	14 Jan 2021 17:57:05

US3342023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered empty.	Ethan Shotton (b) (4)	14 Jan 2021 17:57:05

US3342023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	14 Jan 2021 17:57:24

US3342023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'I'	System	14 Jan 2021 17:57:24

US3342023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered '1'	System	14 Jan 2021 17:57:24
DataPoint set to visible.	System	14 Jan 2021 17:57:24

US3342023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:05:26

US3342023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Per response is noted, however, please note that the sample dated 01FEB2021 is present under OL-D29 Visit in PPD GCL and the same sample data is not entered in EDC. Please update the sample date in EDC under appropriate Visit, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:11:41
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Per response is noted, however, please note that the sample dated 01FEB2021 is present under OL-D29 Visit in PPD GCL and the same sample data is not entered in EDC. Please update the sample date in EDC under appropriate Visit, else clarify.' answered with 'sample collected in error, PD logged & coordinator retrained. data entered as unscheduled 01Feb2021 because unable to add to OL-D29 folder.' (Site from DM).	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:29:00
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Per response is noted, however, please note that the sample dated 01FEB2021 is present under OL-D29 Visit in PPD GCL and the same sample data is not entered in EDC. Please update the sample date in EDC under appropriate Visit, else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 10:35:36
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 10:35:36

US3342023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' answered with '1F652795485' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 19:58:22
User entered '01 Feb 2021'	Paul Pickrell (b) (4) (b) (4) (b) (4), (b) (6)	12 Mar 2021 23:47:10 01 Feb 2021 19:05:26

US3342023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:05:26

US3342023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'OLD29'	System	01 Feb 2021 19:05:26

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '10:25'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '01 Feb 2021 10:25'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '72'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'bpm'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'breaths/min'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '135'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'mmHg'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '84'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'mmHg'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '12:01'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '01 Feb 2021 12:01'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '68'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'bpm'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'breaths/min'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '149'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'mmHg'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '85'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'mmHg'	System	01 Feb 2021 19:09:32

US3342023

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:57

US3342023

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:57

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

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)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'mRNA-1273'	System	01 Feb 2021 19:10:35
DataPoint set to visible.	System	14 Jan 2021 17:57:24

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '11:29'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '01 Feb 2021 11:29'	System	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'ONCE'	System	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 19:10:35

US3342023

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:05:01

US3342023

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'I'	System	01 Feb 2021 19:05:01

US3342023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:58:02

US3342023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:58:02

US3342023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:58:02

US3342023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:58:02

US3342023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:58:06

US3342023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:38
User entered 'I'	System	09 Feb 2021 18:58:06

US3342023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	John Luna (b) (4)	10 Mar 2021 20:06:04

US3342023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '10 Mar 2021'	John Luna (b) (4)	10 Mar 2021 20:06:04

US3342023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Clinic (Clinic)'	John Luna (b) (4)	10 Mar 2021 20:06:04

US3342023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'OLD57'	System	10 Mar 2021 20:06:04

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '10 Mar 2021'	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '10:24'	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '10 Mar 2021 10:24'	System	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '98.0' F	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Oral (Oral)'	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '76'	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'bpm'	System	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '12'	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'breaths/min'	System	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '119'	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'mmHg'	System	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '76'	John Luna (b) (4)	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered 'mmHg'	System	10 Mar 2021 20:06:54

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08

US3342023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08

US3342023

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	John Luna (b) (4)	10 Mar 2021 20:07:10

US3342023

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	John Luna (b) (4)	10 Mar 2021 20:07:10

US3342023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Sample dated 10-Mar-2021 under OL-D57 is still missing in PPD Central Labs. Please provide Accession number details.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 06:51:12
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Sample dated 10-Mar-2021 under OL-D57 is still missing in PPD Central Labs. Please provide Accession number details.' answered with 'per previous query response, sample was received by PPD & accession number 1F619520245.' (Site from DM).	Olivia Hapanowicz (b) (4)	29 Mar 2021 12:25:08
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Sample dated 10-Mar-2021 under OL-D57 is still missing in PPD Central Labs. Please provide Accession number details.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:25:09
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10-Mar-2021 is recorded under OL-D57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	29 Mar 2021 06:25:09
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10-Mar-2021 is recorded under OL-D57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	Olivia Hapanowicz (b) (4)	23 Mar 2021 13:00:02
' answered with 'sample was received, req number 1F619520245' (Site from DM).	(b) (4)	

US3342023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10-Mar-2021 is recorded under OL-D57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 05:02:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:35:19

US3342023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '10 Mar 2021'	Ethan Shotton (b) (4)	11 Mar 2021 13:35:19

US3342023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '10:47'	Ethan Shotton (b) (4)	11 Mar 2021 13:35:19

US3342023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:09:08
User entered '10 Mar 2021 10:47'	System	11 Mar 2021 13:35:19

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:06:01

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '01 Feb 2021'	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:27:02

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:06:01

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '0'	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:27:02

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:06:01

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '0'	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:27:02

US3342023

Folder: **Unscheduled 01 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:06:01**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'I'	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:27:02

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:06:01

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '0'	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:27:02

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:27:23

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '01 Feb 2021'	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:27:23

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '10:57'	Olivia Hapanowicz (b) (4)	06 Apr 2021 18:27:23

US3342023

Folder: Unscheduled 01 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:12
User entered '01 Feb 2021 10:57'	System	06 Apr 2021 18:27:23

US3342023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:06:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:19
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	30 Sep 2020 17:49:28

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:51:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:51:49
Data point term sent to Coder	System	30 Sep 2020 17:50:56
User entered 'right meniscal tear'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '23 Sep 2020'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:50:42

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 21:31:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 21:31:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 13:56:10
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'this AE was verified to still be ongoing as of 01 FEB 2021.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	05 Feb 2021 17:06:16
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:50:48
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	30 Sep 2020 17:50:42

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 21:31:14
User entered '02 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 21:31:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4)	
	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:50:42

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Ethan Shotton (b) (4)	30 Sep 2020 17:50:42

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered 'None (NONE)'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '1'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered '1' reason for change: New Information	Stefanie Mott (b) (4)	05 Jan 2021 17:31:16
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Outcome](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 21:31:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 21:31:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Ethan Shotton (b) (4) (b) (4)	30 Sep 2020 17:50:42

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:50:42
	(b) (4)	

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Sep 2020 17:50:42

US3342023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 17:50:42

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 20:13:56
Data point term sent to Coder	(b) (4)	
User entered 'Depression'	System	10 Mar 2021 20:13:20
	John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Yes (Y)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '16 Feb 2021'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Yes (Y)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Related (NOT RELATED)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Related (NOT RELATED)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '1'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:12:37

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 04:15:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 04:15:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
Data point term sent to Coder	System (b) (4)	10 Mar 2021 20:14:22
User entered 'Worsening of Symptoms: Hypertension'	John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Yes (Y)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '16 Feb 2021'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Yes (Y)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Related (NOT RELATED)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Related (NOT RELATED)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'I'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:29:45
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:06:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 20:13:56

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:14:16
User entered 'USA-US203-2021-mRNA-1273-P301000013'	System	06 Apr 2021 19:14:09
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 19:14:09

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:09:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:09:51
Data point term sent to Coder	System	05 Apr 2021 21:26:59
User entered 'R KNEE OSTEOARTHRITIS'	(b) (4), (b) (6) (b) (4)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

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) (b) (4), (b) (6)	14 Apr 2021 14:28:05
	(b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:28:26
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Narrative](#)

Audit	User	Time (GMT)
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)	14 Apr 2021 14:27:41
User entered 'pt went to the er on 23 sep2020 and was diagnosed with both a R Knee meniscal tear and R knee osteoarthritis. Pt was 1st treated for meniscal tear by physician (see meniscal tear ae). After having meniscectomy procedure pt was still having pain to r knee and discussed with physician total r knee replacement. Pt ultimately decided on replacement on 01APR2021. Pt stated that this was an inpatient surgery. This ae became an sae.' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 21:56:08
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:06:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 21:26:42

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 21:40:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 21:40:55
Data point term sent to Coder	System	05 Apr 2021 21:29:01
User entered 'L KNEE OSTEOARTHRITIS'	(b) (4), (b) (6) (b) (4)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	05 Apr 2021 21:28:16
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 21:28:16
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	05 Apr 2021 21:28:02
User entered '23 Sep 2021'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Please update Dosing discontinuation form accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 12:37:53
Query 'Per CDM: Please update Dosing discontinuation form accordingly.' answered with 'DATA ENTERED IN ERROR. HAS BEEN UPDATED. PLEASE REMOVE QUERY. THANK YOU' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:10:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:09:35
User opened query 'Per CDM: Please update Dosing discontinuation form accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 08:04:21
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

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	05 Apr 2021 21:28:16
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 21:28:16
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Apr 2021 21:28:02
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 21:28:02

US3342023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:06:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 21:28:02

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:06:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:19
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Tiffany Lemuz (b) (4)	13 Aug 2020 13:52:38
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:24:11

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 13:55:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:55:21
Data point term sent to Coder	System	13 Aug 2020 13:54:06
User entered 'Meloxicam'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Osteoarthritis'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '15'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'mg (mg)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:22:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 13:53:21
User entered 'un UNK 2017'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 13:53:21

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
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.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 13:55:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:55:21
Data point term sent to Coder	System	13 Aug 2020 13:54:09
User entered 'Lisinopril'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Hypertension'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '20'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'mg (mg)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'once daily (QD)'	(b) (4) Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:22:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 13:53:55
User entered 'un UNK 2017'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 13:53:55

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 00:33:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:33:14
Data point term sent to Coder	System	13 Aug 2020 13:55:10
User entered 'Zyrtec'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Cedar fever'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '10'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'mg (mg)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'as needed (PRN)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 21:23:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 13:54:44
User entered 'un Dec 2000'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 13:54:44

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 05:41:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 05:41:39
Data point term sent to Coder	System	30 Sep 2020 17:54:08
User entered 'Ibuprofen'	Ethan Shotton (b) (4) (b) (4)	30 Sep 2020 17:53:41

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'right meniscal tear (AE)'	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '400'	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'mg (mg)'	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'once daily (QD)'	(b) (4) Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '23 Sep 2020'	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	30 Sep 2020 17:53:41
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) Ethan Shotton (b) (4)	30 Sep 2020 17:53:41

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 17:53:41

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 17:53:41

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 17:53:41

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:08:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:08:59
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:47:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:30:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:30:24
Data point term sent to Coder	System	06 Oct 2020 16:08:05
User entered 'Cortisone'	Andrew Bell (b) (4) (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Right meniscal tear (AE)'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'I'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Other (OTHER)'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'injection'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'once (ONCE)'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Andrew Bell (b) (4)	06 Oct 2020 16:08:01
	(b) (4)	

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '24 Sep 2020'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '0'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '24 Sep 2020'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	Andrew Bell (b) (4)	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User entered empty.	System	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User entered empty.	System	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:41
User entered empty.	System	06 Oct 2020 16:08:01

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:16:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:16:16
Data point term sent to Coder	System	02 Nov 2020 21:35:43
User entered 'Celecoxib'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Right meniscal tear (AE)'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '100'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'mg (mg)'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'once daily (QD)'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '20 Oct 2020'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '0'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:29:41
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:29:41
User entered empty.	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	Ethan Shotton (b) (4)	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User entered '1'	System	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User entered '1'	System	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:46
User entered '804 (804)'	System	02 Nov 2020 21:34:58

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
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)	05 Jan 2021 17:32:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:32:31
Data point term sent to Coder	System	05 Jan 2021 17:31:03
User entered 'influenza vaccine'	Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User closed query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:43:21
Query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' answered with 'Updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	14 Jan 2021 16:09:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	14 Jan 2021 16:09:50
User opened query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 13:39:34
User entered 'No (N)'	Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'influenza prevention'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '0.5'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'mL (mL)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'once (ONCE)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '18 Oct 2020'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '0'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '18 Oct 2020'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User entered empty.	System	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User entered empty.	System	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:51
User entered empty.	System	05 Jan 2021 17:30:46

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Mar 2021 06:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 06:54:44
Data point term sent to Coder	System	10 Mar 2021 20:09:13
User entered 'Zoloft'	John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'AE: Depression'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '50'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'mg (mg)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'once daily (QD)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Oral (ORAL)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '16 Feb 2021'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Mar 2021 20:08:59

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:59:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:59:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:47:10
Data point term sent to Coder	System	10 Mar 2021 20:11:16
User entered 'Hydrochlorothiazide'	John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'AE: Worsening Symptoms of Hypertension'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '25'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'mg (mg)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'once daily (QD)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Oral (ORAL)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '16 Feb 2021'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '0'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) John Luna (b) (4)	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Mar 2021 20:10:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 04:11:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:11:42
Data point term sent to Coder	System	05 Apr 2021 21:20:22
User entered 'OXYCODONE'	(b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'R KNEE OSTEOARTHRITIS SAE'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '5'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'EVERY 4 HOURS'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:19:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 11:20:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:20:50
Data point term sent to Coder	System	05 Apr 2021 21:21:27
User entered 'COLACE'	(b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'R KNEE OSTEOARTHRITIS SAE'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'SOFTGEL'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'EVERY 6 HOURS'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:20:34

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 04:31:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:31:43
Data point term sent to Coder	System	05 Apr 2021 21:21:32
User entered 'ASPIRIN'	(b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'R KNEE OSTEOARTHRITIS SAE'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '325'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 21:21:29

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:06:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:19
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:32:11
User entered 'No (N)'	Tiffany Lemuz (b) (4)	11 Aug 2020 19:24:21

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:30
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered '2 Nov 2020' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:43:47
User entered '5 Jan 2021'	Stefanie Mott (b) (4)	05 Jan 2021 17:43:32

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:30
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'right meniscus surgery'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:43:32

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:30
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered 'Adverse Event (AE)'	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:43:32

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:01

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:30
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:47:10
User entered empty.	(b) (4) Stefanie Mott (b) (4)	05 Jan 2021 17:43:32

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:17:32

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Total R Knee Replacement'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:17:32

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:17:32

US3342023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:01

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:17:32

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'USA-US203-2021-MRNA-1273-P301000013'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'Yes (Y)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'Yes (Y)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'Paul'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'Pickrell'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'US'	(b) (4) System	06 Apr 2021 19:14:46

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 19:14:46

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'USA-US203-2021-MRNA-1273-P301000013'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'Yes (Y)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'Yes (Y)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'No (N)'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'Paul'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:30
User entered 'Pickrell'	System	06 Apr 2021 19:14:09

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'US'	(b) (4) System	06 Apr 2021 19:14:46

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 19:14:46

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered '06/Apr/2021 15:14'	(b) (4) System	06 Apr 2021 19:14:46

US3342023

Folder: SAE USA-US203-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:25:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:14:46