

US3032323 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:54:53

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US3032323

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

[Participant ID](#)

US3032323

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

US3032323

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Date of Birth (MMM yyyy)	(b) (6) 2000
Age	19
Age Units	YEARS
Age (Derived)	19
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) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Date of Informed Consent (*dd MMM yyyy*) 22 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3032323

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3032323

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Condition	IRREGULAR MENSTRAL CYCLE
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032323

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:53:58

Generated On: 09 Jun 2021 14:54:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:59 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 12:59
Height (<i>xxx.x</i>)	171.5 cm
Weight (<i>xxx.x</i>)	88.5 kg
BMI (<i>xxx.x</i>)	30.08950 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) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 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) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Date of assessment (*dd MMM yyyy*) 22 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 22 AUG 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 18:15:44

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 18:15:44

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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Nov 2020 22:25:37

Generated On: 09 Jun 2021 14:54:53

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 107526

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) 14 Oct 2020 19:46:13

Generated On: 09 Jun 2021 14:54:53

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) 14 Oct 2020 19:46:13

Generated On: 09 Jun 2021 14:54:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:59 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 12:59
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Oct 2020 19:46:13

Generated On: 09 Jun 2021 14:54:53

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 (<i>dd MMM yyyy</i>)	22 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:10 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 15:10
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 13 Oct 2020 14:10:28

Generated On: 09 Jun 2021 14:54:53

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) _____

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 14:36 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 14:36

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) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 AUG 2020

Collection time (*00:00-23:59*) 14:01 (24 HR)

Collection date and time (derived) 22 AUG 2020 14:01

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Collection date (<i>dd MMM yyyy</i>)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:39	22 AUG 2020 13:39
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

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 14:54:53

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

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

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

PC Time Stamp	22 AUG 2020 15:06
PC Open Date & Time	22 AUG 2020 14:56
PC Close Date & Time	22 AUG 2020 17:26

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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 97.1 °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	23 AUG 2020 10:14
PC Open Date & Time	22 AUG 2020 18:21
PC Close Date & Time	23 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 AUG 2020 10:15
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

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	24 AUG 2020 14:10
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 AUG 2020 14:04
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

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

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

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

PC Time Stamp	26 AUG 2020 14:20
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 AUG 2020 23:07
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 AUG 2020 00:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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	22 AUG 2020 15:06
PC Open Date & Time	22 AUG 2020 14:56
PC Close Date & Time	22 AUG 2020 17:26

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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	23 AUG 2020 10:16
PC Open Date & Time	22 AUG 2020 18:21
PC Close Date & Time	23 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	24 AUG 2020 10:16
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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	24 AUG 2020 14:11
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

25 AUG 2020 14:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

26 AUG 2020 14:20

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

27 AUG 2020 23:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

29 AUG 2020 00:00

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

No

Yes

PC Time stamp	22 AUG 2020 16:05
PC Open Date & Time	22 AUG 2020 14:56
PC Close Date & Time	22 AUG 2020 17:26

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

No

Yes

PC Time stamp	23 AUG 2020 10:16
PC Open Date & Time	22 AUG 2020 18:21
PC Close Date & Time	23 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 10:16
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 14:11
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

Yes

PC Time stamp	25 AUG 2020 14:05
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 14:20
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	27 AUG 2020 23:08
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 00:01
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3032323

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 SEP 2020

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

Folder OID VISIT2

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:52 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:52
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:13 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 13:13
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3032323

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 24 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 12:35 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 12:35

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

US3032323

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:15 (24 HR)
Collection date and time (derived)	24 SEP 2020 11:15

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Collection date (<i>dd MMM yyyy</i>)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:59	24 SEP 2020 10:59
Nasopharyngeal Swab 2	No		

US3032323

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:15:44

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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 24 SEP 2020 13:13

PC Open Date & Time 24 SEP 2020 12:55

PC Close Date & Time 24 SEP 2020 15:25

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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 97.7 °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 24 SEP 2020 17:51
PC Open Date & Time 24 SEP 2020 16:20
PC Close Date & Time 25 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 SEP 2020 12:09
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

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

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

PC Time Stamp	26 SEP 2020 22:26
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

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

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

Yes

No

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

PC Time Stamp 28 SEP 2020 01:00

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

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

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

Yes

No

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

PC Time Stamp 28 SEP 2020 23:59

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 SEP 2020 00:19
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

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

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

Yes

No

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

PC Time Stamp

30 SEP 2020 14:19

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

24 SEP 2020 13:13

PC Open Date & Time

24 SEP 2020 12:55

PC Close Date & Time

24 SEP 2020 15:25

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

24 SEP 2020 17:51

PC Open Date & Time

24 SEP 2020 16:20

PC Close Date & Time

25 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	25 SEP 2020 12:09
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	26 SEP 2020 22:26
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

28 SEP 2020 01:00

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	29 SEP 2020 00:00
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

30 SEP 2020 00:19

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

30 SEP 2020 14:19

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

No

Yes

PC Time stamp	24 SEP 2020 13:13
PC Open Date & Time	24 SEP 2020 12:55
PC Close Date & Time	24 SEP 2020 15:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

No

Yes

PC Time stamp	24 SEP 2020 17:52
PC Open Date & Time	24 SEP 2020 16:20
PC Close Date & Time	25 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 12:10
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 22:26
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 01:01
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 00:19
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 14:19
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3032323

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Oct 2020 22:10:24

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 01 Oct 2020 22:10:24

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Oct 2020 14:10:28

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Oct 2020 14:10:28

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 15:06:40

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 15:06:40

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 15:06:40

Generated On: 09 Jun 2021 14:54:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 OCT 2020

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

Folder OID VISIT3

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 15:06:40

Generated On: 09 Jun 2021 14:54:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:53 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 13:53
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032323

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 15:06:40

Generated On: 09 Jun 2021 14:54:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3032323

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 15:06:40

Generated On: 09 Jun 2021 14:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	19 OCT 2020
Collection time (<i>00:00-23:59</i>)	14:09 (24 HR)
Collection date and time (derived)	19 OCT 2020 14:09

US3032323

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 15:06:40

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 22 OCT 2020 00:01:21

Patient Cloud Open Date & Time 22 OCT 2020 00:01

Patient Cloud Close Date & Time 26 OCT 2020 23:59

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 29 OCT 2020 00:46:27

Patient Cloud Open Date & Time 29 OCT 2020 00:01

Patient Cloud Close Date & Time 02 NOV 2020 23:59

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 05 NOV 2020 00:03:04

Patient Cloud Open Date & Time 05 NOV 2020 00:01

Patient Cloud Close Date & Time 09 NOV 2020 23:59

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 92

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

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

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

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

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

Date and time of submission 19 NOV 2020 00:01:33

Patient Cloud Open Date & Time 19 NOV 2020 00:01

Patient Cloud Close Date & Time 23 NOV 2020 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 00:07:00
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 30 NOV 2020 00:05:59

Patient Cloud Open Date & Time 30 NOV 2020 00:01

Patient Cloud Close Date & Time 04 DEC 2020 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 07 DEC 2020 01:26:26

Patient Cloud Open Date & Time 07 DEC 2020 00:01

Patient Cloud Close Date & Time 11 DEC 2020 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 00:47:19
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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	21 DEC 2020 00:33:36
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 00:01:21
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 04:54:42
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 11 JAN 2021 02:54:15

Patient Cloud Open Date & Time 11 JAN 2021 00:01

Patient Cloud Close Date & Time 15 JAN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

18 JAN 2021 00:11:20

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 159

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

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

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

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

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

Date and time of submission 25 JAN 2021 11:08:03

Patient Cloud Open Date & Time 25 JAN 2021 00:01

Patient Cloud Close Date & Time 29 JAN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

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

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

Date and time of submission 01 FEB 2021 00:39:51

Patient Cloud Open Date & Time 01 FEB 2021 00:01

Patient Cloud Close Date & Time 05 FEB 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

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

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

Date and time of submission 08 FEB 2021 00:02:02

Patient Cloud Open Date & Time 08 FEB 2021 00:01

Patient Cloud Close Date & Time 12 FEB 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 180

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

No

Yes

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

No

Yes

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

Date and time of submission 15 FEB 2021 08:15:54

Patient Cloud Open Date & Time 15 FEB 2021 00:01

Patient Cloud Close Date & Time 19 FEB 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 22 FEB 2021 10:29:09

Patient Cloud Open Date & Time 22 FEB 2021 00:01

Patient Cloud Close Date & Time 26 FEB 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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	01 MAR 2021 06:03:18
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 06:02:28
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 15 MAR 2021 05:04:21

Patient Cloud Open Date & Time 15 MAR 2021 00:01

Patient Cloud Close Date & Time 19 MAR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 05:39:08
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 05:02:51
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 07 APR 2021 17:00:20

Patient Cloud Open Date & Time 05 APR 2021 00:01

Patient Cloud Close Date & Time 09 APR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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	12 APR 2021 11:32:13
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 14:20:05
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 05:02:40
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 05:02:44
Patient Cloud Open Date & Time	03 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	31 MAY 2021 00:01
Patient Cloud Close Date & Time	04 JUN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	07 JUN 2021 00:01
Patient Cloud Close Date & Time	11 JUN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

Patient Cloud Open Date & Time	05 JUL 2021 00:01
Patient Cloud Close Date & Time	09 JUL 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	19 JUL 2021 00:01
Patient Cloud Close Date & Time	23 JUL 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	26 JUL 2021 00:01
Patient Cloud Close Date & Time	30 JUL 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

[Patient Cloud Close Date & Time](#) 06 AUG 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	16 AUG 2021 00:01
Patient Cloud Close Date & Time	20 AUG 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

[Patient Cloud Close Date & Time](#) 27 AUG 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	30 AUG 2021 00:01
Patient Cloud Close Date & Time	03 SEP 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	06 SEP 2021 00:01
Patient Cloud Close Date & Time	10 SEP 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	13 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	08 NOV 2021 00:01
Patient Cloud Close Date & Time	12 NOV 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 460

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	03 DEC 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 31 DEC 2021 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JAN 2022 00:01
Patient Cloud Close Date & Time	21 JAN 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 28 JAN 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	31 JAN 2022 00:01
Patient Cloud Close Date & Time	04 FEB 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	07 FEB 2022 00:01
Patient Cloud Close Date & Time	11 FEB 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

Patient Cloud Open Date & Time	14 FEB 2022 00:01
Patient Cloud Close Date & Time	18 FEB 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	07 MAR 2022 00:01
Patient Cloud Close Date & Time	11 MAR 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#) 18 MAR 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	04 APR 2022 00:01
Patient Cloud Close Date & Time	08 APR 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 600

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	13 MAY 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 24 JUN 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2022 00:01
Patient Cloud Close Date & Time	08 JUL 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2022 00:01
Patient Cloud Close Date & Time	26 AUG 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 740

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

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

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

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

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

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#) 09 SEP 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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°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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2022 00:01
Patient Cloud Close Date & Time	30 SEP 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2022 00:01
Patient Cloud Close Date & Time	07 OCT 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2022 00:01
Patient Cloud Close Date & Time	21 OCT 2022 23:59

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 28 OCT 2022 23:59

US3032323

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:54:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 06:03:27

US3032323

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Dec 2020 19:49:18

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Dec 2020 19:49:18

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Dec 2020 15:56:54

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Dec 2020 15:56:54

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3032323

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 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

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032323

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

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.

US3032323

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 1 APR 2021

Collection time (*00:00-23:59*) 14:23 (24 HR)

Collection date and time (derived) 1 APR 2021 14:23

US3032323

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032323

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

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 _____

US3032323

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3032323

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:54:53

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"/>

US3032323

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:54:53

Generate Next COVID-19 Assessment

Yes

No

US3032323

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

Form: Visit Date

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 FEB 2021

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

Folder OID UNBLND_DECIDE

US3032323

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:41:31

Generated On: 09 Jun 2021 14:54:53

Date of updated informed consent (*dd MMM yyyy*) 23 FEB 2021

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

Was the participant unblinded? Yes
No

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

Date of unblinding (*dd MMM yyyy*) 23 FEB 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3032323

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 FEB 2021

Collection time (*00:00-23:59*) 14:50 (24 HR)

Collection date and time (derived) 23 FEB 2021 14:50

US3032323

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	23 FEB 2021
Collection time (<i>00:00 - 23:59</i>)	14:35
Collection Date and Time (derived)	23 FEB 2021 14:35

US3032323

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Mar 2021 16:05:56

Generated On: 09 Jun 2021 14:54:53

AEID USA-US032-2021-MRNA-1273-P30
1000010

Adverse event SPONTANEOUS ABORTION OF PREGNANCY

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) 02 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) 02 FEB 2021

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

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EAB) (1725)

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Mar 2021 16:05:56

Generated On: 09 Jun 2021 14:54:53

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Mar 2021 16:05:56

Generated On: 09 Jun 2021 14:54:53

THE SUBJECT REPORTS SHE WAS EXPERIENCING ABNORMAL SYMPTOMS SUCH AS BLOATING, NAUSEA, AND SOME UPPER RESPIRATORY SYMPTOMS. SHE SAW HER PCP WHO PERFORMED A COVID TEST (NEGATIVE) AND PREGNANCY TEST (POSITIVE). THE SUBJECT WAS UNSURE OF THE DATE SHE SAW PCP. ON 02FEB2021 THE SUBJECT EXPERIENCED HEAVY CRAMPING AND BLEEDING. SHE CONTACTED AN OBGYN WHO CONFIRMED A SPONTANEOUS MISCARRIAGE HAD OCCURRED. SHE IS A NEGATIVE BLOOD TYPE AND WAS GIVEN A ONE TIME DOSE OF RHOGAM. THE SUBJECT REPORTS SHE HAD NOT RECEIVED AN ULTRASOUND PRIOR TO THE MISCARRIAGE. RECORDS ARE PENDING AND WILL UPDATE ONCE RECEIVED.

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)	

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 04 Mar 2021 16:05:56

Generated On: 09 Jun 2021 14:54:53

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

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)

15 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

23 JAN 2021

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

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EAB) (1725)

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 04 Mar 2021 16:05:56

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

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

Yes

No

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

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

Name of Medication LORYNA
"DROSPIRENONE"

Prophylaxis Yes
No

Indication BIRTH CONTROL

Dose per administration 3

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

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2018

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

Name of Medication RHO GAM

Prophylaxis Yes
No

Indication POSTPARTUM RH
PROPHYLAXIS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify AMPULE

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

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:46:00

Generated On: 09 Jun 2021 14:54:53

	Intraocular	<input type="radio"/>
	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) 03 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 03 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032323

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 18:15:43

Generated On: 09 Jun 2021 14:54:53

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3032323

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:54:53

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

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

SAEID	USA-US032-2021-MRNA-1273-P30 1000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

SAEID	USA-US032-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/FEB/2021 12:47
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

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

SAEID	USA-US032-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/MAR/2021 10:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 04 Mar 2021 16:05:57

Generated On: 09 Jun 2021 14:54:53

SAEID	USA-US032-2021-MRNA-1273-P30 1000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/MAR/2021 11:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3032323 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032323

Form: Participant Creation

Generated On: 09 Jun 2021 14:54:53

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'US3032323'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:14:09

US3032323

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:07

US3032323

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:14:10

US3032323

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:07

US3032323

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'SCRN'	System	22 Aug 2020 19:42:07

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '(b) (6)2000'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:14:11

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '19'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35
	(b) (4)	

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'YEARS'	System	22 Aug 2020 19:42:35

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered '19'	System	22 Aug 2020 19:43:15

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Female (F)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35
	(b) (4)	

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:42:35

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '1'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35
	(b) (4)	

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35
	(b) (4)	

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35
	(b) (4)	

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35
	(b) (4)	

US3032323

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:53

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:42:35
	(b) (4)	

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:43:15

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'Aug 2020'	System	22 Aug 2020 19:43:15

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered '2020'	System	22 Aug 2020 19:43:15

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Amendment 2 (2)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:43:15

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:43:15

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:43:15

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:43:15
	(b) (4)	

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:43:15

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:14:10

US3032323

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered '1'	System	22 Aug 2020 19:43:26

US3032323

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:43:26
	(b) (4)	

US3032323

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:54:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:26:48

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
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.	(b) (4) Coder Import (b) (4)	22 Aug 2020 20:31:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 20:31:18
Data point term sent to Coder	System	22 Aug 2020 20:30:18
User entered 'seasonal allergies'	Kelsey Kelley (b) (4)	22 Aug 2020 20:29:38
	(b) (4)	

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'un UNK 2001'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:29:38

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:29:38

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:29:38
	(b) (4)	

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:29:38
	(b) (4)	

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:29:38
	(b) (4)	

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'Jan 2001'	System	22 Aug 2020 20:29:38

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered '2001'	System	22 Aug 2020 20:29:38

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered empty.	System	22 Aug 2020 20:29:38

US3032323

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered empty.	System	22 Aug 2020 20:29:38

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Menstruation irregular, LLT: Irregular menstrual cycle - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 21:44:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 21:44:46
Data point term sent to Coder System	System	02 Mar 2021 21:44:16
User entered 'irregular menstrual cycle'	Samantha Wieseler (b) (4)	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'UN UNK 2014'	(b) (4) Samantha Wieseler (b) (4)	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'Jan 2014'	System	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered '2014'	System	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered empty.	System	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered empty.	System	02 Mar 2021 21:43:32

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19
	(b) (4)	

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19
	(b) (4)	

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '12:59'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered '22 Aug 2020 12:59'	System	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '171.5' cm	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19
DataPoint set to visible.	(b) (4) System	22 Aug 2020 19:43:26

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '88.5' kg	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19
DataPoint set to visible.	(b) (4) System	22 Aug 2020 19:43:26

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
Amendment Manager: User entered '30.08950'	System	17 Sep 2020 00:20:11
User entered '30.1'	System	22 Aug 2020 20:27:19
DataPoint set to visible.	System	22 Aug 2020 19:43:26

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'kg/m2'	System	22 Aug 2020 20:27:19
DataPoint set to visible.	System	22 Aug 2020 19:43:26

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:58
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:28:19
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:36:54
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:36:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:36:47
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:35:50
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered '36.8' C	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:58
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19
	(b) (4)	

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:58
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '62'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'bpm'	System	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:58
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'breaths/min'	System	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:58
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '122'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'mmHg'	System	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:58
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:36:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'mmHg'	System	22 Aug 2020 20:27:19

US3032323

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26

US3032323

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:54
	(b) (4)	

US3032323

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:54
	(b) (4)	

US3032323

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:25:35

US3032323

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:25:35

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:25:35
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:54:53

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:25:35
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:25:35
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:54:53

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:25:35

US3032323

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:25:35

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:54:53

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:25:35

US3032323

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:26:25
	(b) (4)	

US3032323

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:26:25
	(b) (4)	

US3032323

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Urine (URINE)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:26:25
	(b) (4)	

US3032323

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:26:25

US3032323

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:26:25
	(b) (4)	

US3032323

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:26:25

US3032323

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:26:25

US3032323

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered empty.	System	22 Aug 2020 20:26:25

US3032323

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

US3032323

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:53

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54

US3032323

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:53

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

US3032323

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:53

[Manufacturing & Production Operations](#) with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54

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Folder: Screening

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:24:54

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '1'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:24:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:53

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:24:54

US3032323

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:43:35

US3032323

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:43:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:43:35

US3032323

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'VISIT1'	System	22 Aug 2020 19:43:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 19:14:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '107526'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 19:14:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 19:14:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:53

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)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:34

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Folder: Visit 1 Day 1

Form: Randomization

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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)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:34
	(b) (4)	

US3032323

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:34

US3032323

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:34
	(b) (4)	

US3032323

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:53

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:25:37
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 08:51:48
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 15:19:56
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 15:19:22
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 12:39:45
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:20:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:46:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:10:19
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:35:03
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:34:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:34:52
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:39:15
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered '171.5' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 14:34:58
Signature has been broken.	Kelsey Kelley (b) (4)	13 Oct 2020 14:34:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 14:34:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '88.5' kg	Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:46:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:10:19
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:35:03
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:34:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:34:52
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:39:15
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered '171.5' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 14:34:58
Signature has been broken.	Kelsey Kelley (b) (4)	13 Oct 2020 14:34:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 14:34:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '88.5' kg	Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '12:59'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '22 Aug 2020 12:59'	System	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '62'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'bpm'	System	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'breaths/min'	System	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '122'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03
	(b) (4)	

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:46:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:10:19
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:35:03
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:34:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:34:52
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:39:15
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered '171.5' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 14:34:58
Signature has been broken.	Kelsey Kelley (b) (4)	13 Oct 2020 14:34:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 14:34:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '88.5' kg	Kelsey Kelley (b) (4)	22 Aug 2020 20:28:03

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25
	(b) (4)	

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '15:10'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '22 Aug 2020 15:10'	System	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '66'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'bpm'	System	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'breaths/min'	System	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '111'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '88'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	22 Aug 2020 20:28:25

US3032323

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:45

US3032323

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:45
	(b) (4)	

US3032323

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
User closed query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at VID1. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:42:14
Query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at VID1. Please update accordingly' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:41:34
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:41:26
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:41:26
User opened query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at VID1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:09:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:27:32

US3032323

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:41:26
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:41:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:32

US3032323

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:41:26
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:41:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Urine (URINE)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:32

US3032323

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:41:26
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 15:41:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:32

US3032323

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
User closed query 'Per CDM : Kindly confirm if FSH sample was collected Yes or NO. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 09:18:18
Query 'Per CDM : Kindly confirm if FSH sample was collected Yes or NO. ' answered with 'updated ' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 16:57:11
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 16:57:07
User opened query 'Per CDM : Kindly confirm if FSH sample was collected Yes or NO. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:43:44
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:41:26
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:41:26
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:27:32

US3032323

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:32

US3032323

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:27:32

US3032323

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered empty.	System	22 Aug 2020 20:27:32

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:13

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:13

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

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)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:13
	(b) (4)	

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 19:44:13

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:13
	(b) (4)	

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '14:36'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:13

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '22 Aug 2020 14:36'	System	22 Aug 2020 19:44:13

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:44:13

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'ONCE'	System	22 Aug 2020 19:44:13

US3032323

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 19:44:13

US3032323

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:06

US3032323

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:06
	(b) (4)	

US3032323

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '14:01'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:06

US3032323

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '22 Aug 2020 14:01'	System	22 Aug 2020 20:30:06

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '13:39'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '22 Aug 2020 13:39'	System	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered empty.	System	22 Aug 2020 20:30:19

US3032323

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:30:36

US3032323

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	22 Aug 2020 20:30:36

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T15:06:17', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6fd78c84-a1ca-4cde-9fc8-98b70d2b93ca'	System	22 Aug 2020 20:06:29
User entered 'No (N)'	System	22 Aug 2020 20:06:29

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T15:06:20', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6fd78c84-a1ca-4cde-9fc8-98b70d2b93ca'	System	22 Aug 2020 20:06:29
User entered 'No (N)'	System	22 Aug 2020 20:06:29

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T15:06:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6fd78c84-a1ca-4cde-9fc8-98b70d2b93ca' User entered '22 Aug 2020 15:06'	System	22 Aug 2020 20:06:29
	System	22 Aug 2020 20:06:29

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 14:56'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 17:26'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-23T10:14:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '696dcd13-982a-4a62-88d3-2a0f93ea90a9' User entered 'Yes (Y)'	System	23 Aug 2020 15:14:47
	System	23 Aug 2020 15:14:47

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:14:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '696dcd13-982a-4a62-88d3-2a0f93ea90a9' User entered '97.1'	System	23 Aug 2020 15:14:47
	System	23 Aug 2020 15:14:47

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:14:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '696dcd13-982a-4a62-88d3-2a0f93ea90a9' User entered 'No (N)'	System	23 Aug 2020 15:14:47
	System	23 Aug 2020 15:14:47

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:14:46', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '696dcd13-982a-4a62-88d3-2a0f93ea90a9' User entered '23 Aug 2020 10:14'	System	23 Aug 2020 15:14:47
	System	23 Aug 2020 15:14:47

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 18:21'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 2'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:15:35', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '428a16bf-98a5-441f-b096-99d681e22f57'	System	24 Aug 2020 15:15:55
User entered 'Yes (Y)'	System	24 Aug 2020 15:15:55

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:15:46', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '428a16bf-98a5-441f-b096-99d681e22f57'	System	24 Aug 2020 15:15:55
User entered '97.0'	System	24 Aug 2020 15:15:55

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:15:49', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '428a16bf-98a5-441f-b096-99d681e22f57'	System	24 Aug 2020 15:15:55
User entered 'No (N)'	System	24 Aug 2020 15:15:55

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:15:52', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '428a16bf-98a5-441f-b096-99d681e22f57' User entered '24 Aug 2020 10:15'	System	24 Aug 2020 15:15:55
	System	24 Aug 2020 15:15:55

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 3'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:10:51', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6d3ec28c-7c97-4fd6-97f5-cfd10ca023ac' User entered 'No (N)'	System	24 Aug 2020 19:11:01
	System	24 Aug 2020 19:11:01

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:10:57', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6d3ec28c-7c97-4fd6-97f5-cfd10ca023ac' User entered 'No (N)'	System	24 Aug 2020 19:11:01
	System	24 Aug 2020 19:11:01

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:10:59', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6d3ec28c-7c97-4fd6-97f5-cfd10ca023ac' User entered '24 Aug 2020 14:10'	System	24 Aug 2020 19:11:01
	System	24 Aug 2020 19:11:01

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 4'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-25T14:04:44', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '19c25f8f-4596-43bb-b122-8a2acac62c28' User entered 'Yes (Y)'	System	25 Aug 2020 19:05:19
	System	25 Aug 2020 19:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:04:53', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '19c25f8f-4596-43bb-b122-8a2acac62c28'	System	25 Aug 2020 19:05:19
User entered '98.0'	System	25 Aug 2020 19:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:04:56', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '19c25f8f-4596-43bb-b122-8a2acac62c28'	System	25 Aug 2020 19:05:19
User entered 'No (N)'	System	25 Aug 2020 19:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-25T14:04:58', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '19c25f8f-4596-43bb-b122-8a2acac62c28' User entered '25 Aug 2020 14:04'	System	25 Aug 2020 19:05:19
	System	25 Aug 2020 19:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 5'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:03', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '691ca423-c48e-47c6-a631-6a36e1fd9884' User entered 'No (N)'	System	26 Aug 2020 19:20:11
	System	26 Aug 2020 19:20:11

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:05', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '691ca423-c48e-47c6-a631-6a36e1fd9884'	System	26 Aug 2020 19:20:11
User entered 'No (N)'	System	26 Aug 2020 19:20:11

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-26T14:20:07', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '691ca423-c48e-47c6-a631-6a36e1fd9884' User entered '26 Aug 2020 14:20'	System	26 Aug 2020 19:20:11
	System	26 Aug 2020 19:20:11

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 6'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-27T23:07:43', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c6951d1c-1015-4427-a208-c03a4e518ec9' User entered 'Yes (Y)'	System	28 Aug 2020 04:07:54
	System	28 Aug 2020 04:07:54

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-27T23:07:48', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c6951d1c-1015-4427-a208-c03a4e518ec9' User entered '98.0'	System	28 Aug 2020 04:07:54
	System	28 Aug 2020 04:07:54

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:07:49', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c6951d1c-1015-4427-a208-c03a4e518ec9' User entered 'No (N)'	System	28 Aug 2020 04:07:54
	System	28 Aug 2020 04:07:54

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:07:52', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c6951d1c-1015-4427-a208-c03a4e518ec9' User entered '27 Aug 2020 23:07'	System	28 Aug 2020 04:07:54
	System	28 Aug 2020 04:07:54

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 7'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-29T00:00:14', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '49f8153f-6cd4-401f-96ea-69f65d4f9dae' User entered 'Yes (Y)'	System	29 Aug 2020 05:00:29
	System	29 Aug 2020 05:00:29

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-29T00:00:20', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '49f8153f-6cd4-401f-96ea-69f65d4f9dae' User entered '97.5'	System	29 Aug 2020 05:00:29
	System	29 Aug 2020 05:00:29

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:23', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '49f8153f-6cd4-401f-96ea-69f65d4f9dae'	System	29 Aug 2020 05:00:29
User entered 'No (N)'	System	29 Aug 2020 05:00:29

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-29T00:00:26', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '49f8153f-6cd4-401f-96ea-69f65d4f9dae' User entered '29 Aug 2020 00:00'	System	29 Aug 2020 05:00:29
	System	29 Aug 2020 05:00:29

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T15:06:33', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e1e09d7-a35f-4e88-acfa-d0713798fe5d'	System	22 Aug 2020 20:06:57
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 20:06:57

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T15:06:42', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e1e09d7-a35f-4e88-acfa-d0713798fe5d' User entered 'No (N)'	System	22 Aug 2020 20:06:57
	System	22 Aug 2020 20:06:57

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T15:06:44', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e1e09d7-a35f-4e88-acfa-d0713798fe5d' User entered 'No (N)'	System	22 Aug 2020 20:06:57
	System	22 Aug 2020 20:06:57

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T15:06:53', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e1e09d7-a35f-4e88-acfa-d0713798fe5d'	System	22 Aug 2020 20:06:57
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 20:06:57

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T15:06:55', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e1e09d7-a35f-4e88-acfa-d0713798fe5d' User entered '22 Aug 2020 15:06'	System	22 Aug 2020 20:06:57
	System	22 Aug 2020 20:06:57

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 14:56'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 17:26'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:14:53', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0262cfdc-0dd1-4a0c-aa03-ac3663b5626f' User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 15:16:10
	System	23 Aug 2020 15:16:10

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:15:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0262cfdc-0dd1-4a0c-aa03-ac3663b5626f' User entered 'No (N)'	System	23 Aug 2020 15:16:10
	System	23 Aug 2020 15:16:10

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:15:53', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0262cfdc-0dd1-4a0c-aa03-ac3663b5626f' User entered 'No (N)'	System	23 Aug 2020 15:16:10
	System	23 Aug 2020 15:16:10

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:15:58', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0262cfdc-0dd1-4a0c-aa03-ac3663b5626f' User entered 'None (1)'	System	23 Aug 2020 15:16:10
	System	23 Aug 2020 15:16:10

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:16:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0262cfdc-0dd1-4a0c-aa03-ac3663b5626f' User entered '23 Aug 2020 10:16'	System	23 Aug 2020 15:16:10
	System	23 Aug 2020 15:16:10

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 18:21'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 2'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:15:59', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'afef5a25-63bc-42bf-9939-21cd7c3523ea'	System	24 Aug 2020 15:16:25
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 15:16:25

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:03', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'afef5a25-63bc-42bf-9939-21cd7c3523ea'	System	24 Aug 2020 15:16:25
User entered 'No (N)'	System	24 Aug 2020 15:16:25

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:15', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'afef5a25-63bc-42bf-9939-21cd7c3523ea' User entered 'No (N)'	System	24 Aug 2020 15:16:25
	System	24 Aug 2020 15:16:25

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-24T10:16:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'afef5a25-63bc-42bf-9939-21cd7c3523ea'	System	24 Aug 2020 15:16:25
User entered 'None (1)'	System	24 Aug 2020 15:16:25

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:21', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'afef5a25-63bc-42bf-9939-21cd7c3523ea' User entered '24 Aug 2020 10:16'	System	24 Aug 2020 15:16:25
	System	24 Aug 2020 15:16:25

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 3'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-24T14:11:06', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e5f9719d-9d0e-4b9a-8f35-0475a67390ec'	System	24 Aug 2020 19:11:30
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 19:11:30

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:15', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e5f9719d-9d0e-4b9a-8f35-0475a67390ec'	System	24 Aug 2020 19:11:30
User entered 'No (N)'	System	24 Aug 2020 19:11:30

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:21', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e5f9719d-9d0e-4b9a-8f35-0475a67390ec' User entered 'No (N)'	System	24 Aug 2020 19:11:30
	System	24 Aug 2020 19:11:30

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-24T14:11:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e5f9719d-9d0e-4b9a-8f35-0475a67390ec'	System	24 Aug 2020 19:11:30
User entered 'None (1)'	System	24 Aug 2020 19:11:30

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:27', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e5f9719d-9d0e-4b9a-8f35-0475a67390ec' User entered '24 Aug 2020 14:11'	System	24 Aug 2020 19:11:30
	System	24 Aug 2020 19:11:30

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 4'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:04', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a95cacc7-30eb-4848-b8ca-174ca79b103c'	System	25 Aug 2020 19:05:23
User entered 'None (1)'	System	25 Aug 2020 19:05:23

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:08', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a95cacc7-30eb-4848-b8ca-174ca79b103c' User entered 'No (N)'	System	25 Aug 2020 19:05:23
	System	25 Aug 2020 19:05:23

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a95cacc7-30eb-4848-b8ca-174ca79b103c' User entered 'No (N)'	System	25 Aug 2020 19:05:23
	System	25 Aug 2020 19:05:23

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-25T14:05:17', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a95cacc7-30eb-4848-b8ca-174ca79b103c'	System	25 Aug 2020 19:05:23
User entered 'None (1)'	System	25 Aug 2020 19:05:23

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-25T14:05:19', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a95cacc7-30eb-4848-b8ca-174ca79b103c' User entered '25 Aug 2020 14:05'	System	25 Aug 2020 19:05:23
	System	25 Aug 2020 19:05:23

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 5'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-26T14:20:10', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8bb7aa04-0548-461e-920a-bcc32439d055'	System	26 Aug 2020 19:20:22
User entered 'None (1)'	System	26 Aug 2020 19:20:22

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8bb7aa04-0548-461e-920a-bcc32439d055'	System	26 Aug 2020 19:20:22
User entered 'No (N)'	System	26 Aug 2020 19:20:22

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-26T14:20:14', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8bb7aa04-0548-461e-920a-bcc32439d055'	System	26 Aug 2020 19:20:22
User entered 'No (N)'	System	26 Aug 2020 19:20:22

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-26T14:20:16', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8bb7aa04-0548-461e-920a-bcc32439d055'	System	26 Aug 2020 19:20:22
User entered 'None (1)'	System	26 Aug 2020 19:20:22

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-26T14:20:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8bb7aa04-0548-461e-920a-bcc32439d055' User entered '26 Aug 2020 14:20'	System	26 Aug 2020 19:20:22
	System	26 Aug 2020 19:20:22

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 6'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-27T23:07:57', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e230c716-606b-48ed-88ac-d65745578153'	System	28 Aug 2020 04:08:11
User entered 'None (1)'	System	28 Aug 2020 04:08:11

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-27T23:08:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e230c716-606b-48ed-88ac-d65745578153'	System	28 Aug 2020 04:08:11
User entered 'No (N)'	System	28 Aug 2020 04:08:11

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-27T23:08:02', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e230c716-606b-48ed-88ac-d65745578153'	System	28 Aug 2020 04:08:11
User entered 'No (N)'	System	28 Aug 2020 04:08:11

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-27T23:08:05', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e230c716-606b-48ed-88ac-d65745578153'	System	28 Aug 2020 04:08:11
User entered 'None (1)'	System	28 Aug 2020 04:08:11

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-27T23:08:08', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e230c716-606b-48ed-88ac-d65745578153'	System	28 Aug 2020 04:08:11
User entered '27 Aug 2020 23:08'	System	28 Aug 2020 04:08:11

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 7'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:30', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '9a69ee4b-f196-4c95-a1da-3f8de10b4fc1' User entered 'None (1)'	System	29 Aug 2020 05:00:44
	System	29 Aug 2020 05:00:44

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:33', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '9a69ee4b-f196-4c95-a1da-3f8de10b4fc1' User entered 'No (N)'	System	29 Aug 2020 05:00:44
	System	29 Aug 2020 05:00:44

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:35', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '9a69ee4b-f196-4c95-a1da-3f8de10b4fc1' User entered 'No (N)'	System	29 Aug 2020 05:00:44
	System	29 Aug 2020 05:00:44

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:37', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '9a69ee4b-f196-4c95-a1da-3f8de10b4fc1' User entered 'None (1)'	System	29 Aug 2020 05:00:44
	System	29 Aug 2020 05:00:44

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-29T00:00:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '9a69ee4b-f196-4c95-a1da-3f8de10b4fc1' User entered '29 Aug 2020 00:00'	System	29 Aug 2020 05:00:44
	System	29 Aug 2020 05:00:44

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T16:05:01', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '37288e7f-f593-4da1-b7be-a2d6fb468f47'	System	22 Aug 2020 21:05:19
User entered 'None (0)'	System	22 Aug 2020 21:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T16:05:04', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '37288e7f-f593-4da1-b7be-a2d6fb468f47' User entered 'None (0)'	System	22 Aug 2020 21:05:19
	System	22 Aug 2020 21:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T16:05:06', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '37288e7f-f593-4da1-b7be-a2d6fb468f47'	System	22 Aug 2020 21:05:19
User entered 'None (0)'	System	22 Aug 2020 21:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T16:05:09', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '37288e7f-f593-4da1-b7be-a2d6fb468f47' User entered 'None (0)'	System	22 Aug 2020 21:05:19
	System	22 Aug 2020 21:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T16:05:11', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '37288e7f-f593-4da1-b7be-a2d6fb468f47'	System	22 Aug 2020 21:05:19
User entered 'None (0)'	System	22 Aug 2020 21:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T16:05:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '37288e7f-f593-4da1-b7be-a2d6fb468f47' User entered 'None (0)'	System	22 Aug 2020 21:05:19
	System	22 Aug 2020 21:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T16:05:16', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '37288e7f-f593-4da1-b7be-a2d6fb468f47'	System	22 Aug 2020 21:05:19
User entered 'No (N)'	System	22 Aug 2020 21:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-22T16:05:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '37288e7f-f593-4da1-b7be-a2d6fb468f47' User entered '22 Aug 2020 16:05'	System	22 Aug 2020 21:05:19
	System	22 Aug 2020 21:05:19

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 14:56'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 17:26'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:16:05', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3ad8155a-8843-463a-bd16-404b130e69be' User entered 'None (0)'	System	23 Aug 2020 15:16:32
	System	23 Aug 2020 15:16:32

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:16:08', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3ad8155a-8843-463a-bd16-404b130e69be' User entered 'None (0)'	System	23 Aug 2020 15:16:32
	System	23 Aug 2020 15:16:32

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:16:11', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3ad8155a-8843-463a-bd16-404b130e69be' User entered 'None (0)'	System	23 Aug 2020 15:16:32
	System	23 Aug 2020 15:16:32

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:16:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3ad8155a-8843-463a-bd16-404b130e69be' User entered 'None (0)'	System	23 Aug 2020 15:16:32
	System	23 Aug 2020 15:16:32

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-23T10:16:14', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3ad8155a-8843-463a-bd16-404b130e69be' User entered 'None (0)'	System	23 Aug 2020 15:16:32
	System	23 Aug 2020 15:16:32

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-23T10:16:16', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3ad8155a-8843-463a-bd16-404b130e69be' User entered 'None (0)'	System	23 Aug 2020 15:16:32
	System	23 Aug 2020 15:16:32

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-23T10:16:22', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3ad8155a-8843-463a-bd16-404b130e69be' User entered 'No (N)'	System	23 Aug 2020 15:16:32
	System	23 Aug 2020 15:16:32

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-23T10:16:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3ad8155a-8843-463a-bd16-404b130e69be' User entered '23 Aug 2020 10:16'	System	23 Aug 2020 15:16:32
	System	23 Aug 2020 15:16:32

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '22 Aug 2020 18:21'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 2'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-24T10:16:28', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '972ccaf4-391b-4b48-b69a-ca4ba20eb769' User entered 'None (0)'	System	24 Aug 2020 15:16:50
	System	24 Aug 2020 15:16:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:31', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '972ccaf4-391b-4b48-b69a-ca4ba20eb769' User entered 'None (0)'	System	24 Aug 2020 15:16:50
	System	24 Aug 2020 15:16:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:34', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '972ccaf4-391b-4b48-b69a-ca4ba20eb769' User entered 'None (0)'	System	24 Aug 2020 15:16:50
	System	24 Aug 2020 15:16:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '972ccaf4-391b-4b48-b69a-ca4ba20eb769' User entered 'None (0)'	System	24 Aug 2020 15:16:50
	System	24 Aug 2020 15:16:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:38', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '972ccaf4-391b-4b48-b69a-ca4ba20eb769' User entered 'None (0)'	System	24 Aug 2020 15:16:50
	System	24 Aug 2020 15:16:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:41', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '972ccaf4-391b-4b48-b69a-ca4ba20eb769' User entered 'None (0)'	System	24 Aug 2020 15:16:50
	System	24 Aug 2020 15:16:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:44', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '972ccaf4-391b-4b48-b69a-ca4ba20eb769' User entered 'No (N)'	System	24 Aug 2020 15:16:50
	System	24 Aug 2020 15:16:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T10:16:46', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '972ccaf4-391b-4b48-b69a-ca4ba20eb769' User entered '24 Aug 2020 10:16'	System	24 Aug 2020 15:16:50
	System	24 Aug 2020 15:16:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 3'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:32', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '817642a6-49bc-4f4b-bd32-98601c94913e' User entered 'No interference with activity (1)'	System	24 Aug 2020 19:11:58
	System	24 Aug 2020 19:11:58

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:53', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '817642a6-49bc-4f4b-bd32-98601c94913e' User entered 'No interference with activity (1)'	System	24 Aug 2020 19:11:58
	System	24 Aug 2020 19:11:58

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '817642a6-49bc-4f4b-bd32-98601c94913e' User entered 'None (0)'	System	24 Aug 2020 19:11:58
	System	24 Aug 2020 19:11:58

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '817642a6-49bc-4f4b-bd32-98601c94913e' User entered 'None (0)'	System	24 Aug 2020 19:11:58
	System	24 Aug 2020 19:11:58

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:41', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '817642a6-49bc-4f4b-bd32-98601c94913e' User entered 'None (0)'	System	24 Aug 2020 19:11:58
	System	24 Aug 2020 19:11:58

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:43', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '817642a6-49bc-4f4b-bd32-98601c94913e' User entered 'None (0)'	System	24 Aug 2020 19:11:58
	System	24 Aug 2020 19:11:58

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:47', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '817642a6-49bc-4f4b-bd32-98601c94913e' User entered 'No (N)'	System	24 Aug 2020 19:11:58
	System	24 Aug 2020 19:11:58

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-24T14:11:56', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '817642a6-49bc-4f4b-bd32-98601c94913e' User entered '24 Aug 2020 14:11'	System	24 Aug 2020 19:11:58
	System	24 Aug 2020 19:11:58

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 4'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:22', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4c26a5c8-7472-4fdb-b05a-f2e96d6ac46d' User entered 'None (0)'	System	25 Aug 2020 19:05:48
	System	25 Aug 2020 19:05:48

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:25', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4c26a5c8-7472-4fdb-b05a-f2e96d6ac46d' User entered 'None (0)'	System	25 Aug 2020 19:05:48
	System	25 Aug 2020 19:05:48

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:27', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4c26a5c8-7472-4fdb-b05a-f2e96d6ac46d' User entered 'None (0)'	System	25 Aug 2020 19:05:48
	System	25 Aug 2020 19:05:48

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4c26a5c8-7472-4fdb-b05a-f2e96d6ac46d' User entered 'None (0)'	System	25 Aug 2020 19:05:48
	System	25 Aug 2020 19:05:48

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:37', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4c26a5c8-7472-4fdb-b05a-f2e96d6ac46d' User entered 'None (0)'	System	25 Aug 2020 19:05:48
	System	25 Aug 2020 19:05:48

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:40', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4c26a5c8-7472-4fdb-b05a-f2e96d6ac46d' User entered 'None (0)'	System	25 Aug 2020 19:05:48
	System	25 Aug 2020 19:05:48

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:43', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4c26a5c8-7472-4fdb-b05a-f2e96d6ac46d' User entered 'No (N)'	System	25 Aug 2020 19:05:48
	System	25 Aug 2020 19:05:48

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-25T14:05:45', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4c26a5c8-7472-4fdb-b05a-f2e96d6ac46d' User entered '25 Aug 2020 14:05'	System	25 Aug 2020 19:05:48
	System	25 Aug 2020 19:05:48

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 5'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:22', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '39eb5be8-c5b1-4e5a-b74b-e4aec5211e12' User entered 'None (0)'	System	26 Aug 2020 19:20:41
	System	26 Aug 2020 19:20:41

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '39eb5be8-c5b1-4e5a-b74b-e4aec5211e12' User entered 'None (0)'	System	26 Aug 2020 19:20:41
	System	26 Aug 2020 19:20:41

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:25', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '39eb5be8-c5b1-4e5a-b74b-e4aec5211e12' User entered 'None (0)'	System	26 Aug 2020 19:20:41
	System	26 Aug 2020 19:20:41

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:26', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '39eb5be8-c5b1-4e5a-b74b-e4aec5211e12' User entered 'None (0)'	System	26 Aug 2020 19:20:41
	System	26 Aug 2020 19:20:41

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:28', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '39eb5be8-c5b1-4e5a-b74b-e4aec5211e12' User entered 'None (0)'	System	26 Aug 2020 19:20:41
	System	26 Aug 2020 19:20:41

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:29', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '39eb5be8-c5b1-4e5a-b74b-e4aec5211e12' User entered 'None (0)'	System	26 Aug 2020 19:20:41
	System	26 Aug 2020 19:20:41

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:31', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '39eb5be8-c5b1-4e5a-b74b-e4aec5211e12' User entered 'No (N)'	System	26 Aug 2020 19:20:41
	System	26 Aug 2020 19:20:41

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-26T14:20:34', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '39eb5be8-c5b1-4e5a-b74b-e4aec5211e12' User entered '26 Aug 2020 14:20'	System	26 Aug 2020 19:20:41
	System	26 Aug 2020 19:20:41

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 6'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:08:27', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c24fe43d-e357-4d37-9bc5-65200f8e33cd'	System	28 Aug 2020 04:08:50
User entered 'No interference with activity (1)'	System	28 Aug 2020 04:08:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:08:29', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c24fe43d-e357-4d37-9bc5-65200f8e33cd' User entered 'None (0)'	System	28 Aug 2020 04:08:50
	System	28 Aug 2020 04:08:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:08:31', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c24fe43d-e357-4d37-9bc5-65200f8e33cd' User entered 'None (0)'	System	28 Aug 2020 04:08:50
	System	28 Aug 2020 04:08:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:08:33', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c24fe43d-e357-4d37-9bc5-65200f8e33cd' User entered 'None (0)'	System	28 Aug 2020 04:08:50
	System	28 Aug 2020 04:08:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:08:34', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c24fe43d-e357-4d37-9bc5-65200f8e33cd' User entered 'None (0)'	System	28 Aug 2020 04:08:50
	System	28 Aug 2020 04:08:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:08:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c24fe43d-e357-4d37-9bc5-65200f8e33cd' User entered 'None (0)'	System	28 Aug 2020 04:08:50
	System	28 Aug 2020 04:08:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:08:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c24fe43d-e357-4d37-9bc5-65200f8e33cd' User entered 'No (N)'	System	28 Aug 2020 04:08:50
	System	28 Aug 2020 04:08:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-27T23:08:47', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'c24fe43d-e357-4d37-9bc5-65200f8e33cd' User entered '27 Aug 2020 23:08'	System	28 Aug 2020 04:08:50
	System	28 Aug 2020 04:08:50

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 7'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:43', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1058cdf3-901a-448c-9484-2b329fbd83ff' User entered 'None (0)'	System	29 Aug 2020 05:01:08
	System	29 Aug 2020 05:01:08

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:46', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1058cdf3-901a-448c-9484-2b329fbd83ff' User entered 'None (0)'	System	29 Aug 2020 05:01:08
	System	29 Aug 2020 05:01:08

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:51', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1058cdf3-901a-448c-9484-2b329fbd83ff' User entered 'None (0)'	System	29 Aug 2020 05:01:08
	System	29 Aug 2020 05:01:08

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:53', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1058cdf3-901a-448c-9484-2b329fbd83ff' User entered 'None (0)'	System	29 Aug 2020 05:01:08
	System	29 Aug 2020 05:01:08

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:00:57', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1058cdf3-901a-448c-9484-2b329fbd83ff' User entered 'None (0)'	System	29 Aug 2020 05:01:08
	System	29 Aug 2020 05:01:08

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:01:01', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1058cdf3-901a-448c-9484-2b329fbd83ff' User entered 'None (0)'	System	29 Aug 2020 05:01:08
	System	29 Aug 2020 05:01:08

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-08-29T00:01:04', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1058cdf3-901a-448c-9484-2b329fbd83ff' User entered 'No (N)'	System	29 Aug 2020 05:01:08
	System	29 Aug 2020 05:01:08

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-08-29T00:01:05', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1058cdf3-901a-448c-9484-2b329fbd83ff' User entered '29 Aug 2020 00:01'	System	29 Aug 2020 05:01:08
	System	29 Aug 2020 05:01:08

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 19:44:13

US3032323

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:06

US3032323

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	09 Sep 2020 19:01:36
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).		09 Sep 2020 19:01:36
User entered '31 Aug 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	09 Sep 2020 19:01:36
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	09 Sep 2020 19:01:06
User entered '02 Sep 2020'	Samantha Wieseler (b) (4)	09 Sep 2020 19:01:06
	(b) (4)	

US3032323

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:06

US3032323

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:06
	(b) (4)	

US3032323

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:40

US3032323

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	09 Sep 2020 19:01:40

US3032323

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:51
	(b) (4)	

US3032323

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '08 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:51
	(b) (4)	

US3032323

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:51

US3032323

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:51
	(b) (4)	

US3032323

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 19:01:55

US3032323

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	09 Sep 2020 19:01:55

US3032323

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	14 Sep 2020 21:23:53

US3032323

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '14 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	14 Sep 2020 21:23:53
	(b) (4)	

US3032323

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	14 Sep 2020 21:23:53
	(b) (4)	

US3032323

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	14 Sep 2020 21:23:53
	(b) (4)	

US3032323

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	14 Sep 2020 21:23:58

US3032323

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	14 Sep 2020 21:23:58

US3032323

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:55:18

US3032323

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '24 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:55:18

US3032323

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:55:18

US3032323

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'VISIT2'	System	24 Sep 2020 17:55:18

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:03
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	25 Sep 2020 22:04:23
User entered '24 Sep 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 22:04:23
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 22:04:03
User entered '25 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	25 Sep 2020 22:04:23
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	25 Sep 2020 22:04:03
User entered '10:52'	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '24 Sep 2020 10:52'	System	25 Sep 2020 22:04:23
User entered '25 Sep 2020 10:52'	System	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:03
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '72'	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'bpm'	System	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'breaths/min'	System	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '124'	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '80'	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	25 Sep 2020 22:04:03

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 22:04:23

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Sep 2020 22:05:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 22:05:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	25 Sep 2020 22:05:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Sep 2020 22:04:23
User entered empty.	System	25 Sep 2020 22:04:23
	Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
	(b) (4)	
User entered '24 Sep 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	25 Sep 2020 22:05:02
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '13:13' reason for change: Data Entry Error	(b) (4)	25 Sep 2020 22:05:02
User entered empty.	Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '24 Sep 2020 13:13'	System	25 Sep 2020 22:05:02
User entered empty.	System	25 Sep 2020 22:04:23

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '36.5' C reason for change: Data Entry Error	(b) (4)	25 Sep 2020 22:05:02
User entered empty.	Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	25 Sep 2020 22:05:02
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '67' reason for change: Data Entry Error	(b) (4)	25 Sep 2020 22:05:02
User entered empty.	Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'bpm'	System	25 Sep 2020 22:05:02
User entered empty.	System	25 Sep 2020 22:04:23

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '14' reason for change: Data Entry Error	(b) (4)	25 Sep 2020 22:05:02
User entered empty.	Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'breaths/min'	System	25 Sep 2020 22:05:02
User entered empty.	System	25 Sep 2020 22:04:23

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '107' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:05:02
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	25 Sep 2020 22:05:02
User entered empty.	System	25 Sep 2020 22:04:23

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '84' reason for change: Data Entry Error	(b) (4)	25 Sep 2020 22:05:02
User entered empty.	Kelsey Kelley (b) (4)	25 Sep 2020 22:04:23
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	25 Sep 2020 22:05:02
User entered empty.	System	25 Sep 2020 22:04:23

US3032323

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:28

US3032323

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '24 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:28

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:39

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '24 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:39
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Urine (URINE)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:39

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Negative (NEGATIVE)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:39

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:39

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:39

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:58:39

US3032323

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:54:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered empty.	System	24 Sep 2020 17:58:39

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

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)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '24 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '12:35'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '24 Sep 2020 12:35'	System	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Right Arm (RIGHT ARM)'	Linden DeBoer (b) (4)	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'ONCE'	System	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 17:59:11

US3032323

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	24 Sep 2020 17:59:36

US3032323

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '24 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:36

US3032323

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '11:15'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:36

US3032323

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '24 Sep 2020 11:15'	System	24 Sep 2020 17:59:36

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:54:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '24 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:51

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	24 Sep 2020 17:59:51

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:51

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '10:59'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:51

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '24 Sep 2020 10:59'	System	24 Sep 2020 17:59:51

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	24 Sep 2020 17:59:51

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:51

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:51
	(b) (4)	

US3032323

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered empty.	System	24 Sep 2020 17:59:51

US3032323

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	24 Sep 2020 17:59:54

US3032323

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	24 Sep 2020 17:59:54

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:06', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '10c6b637-d233-4d7a-85f1-76a9e3188c08' User entered 'Yes (Y)'	System	24 Sep 2020 18:13:18
	System	24 Sep 2020 18:13:18

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:11', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '10c6b637-d233-4d7a-85f1-76a9e3188c08' User entered '97.7'	System	24 Sep 2020 18:13:18
	System	24 Sep 2020 18:13:18

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '10c6b637-d233-4d7a-85f1-76a9e3188c08' User entered 'No (N)'	System	24 Sep 2020 18:13:18
	System	24 Sep 2020 18:13:18

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:15', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '10c6b637-d233-4d7a-85f1-76a9e3188c08' User entered '24 Sep 2020 13:13'	System	24 Sep 2020 18:13:18
	System	24 Sep 2020 18:13:18

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '24 Sep 2020 12:55'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '24 Sep 2020 15:25'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:23', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '67d0f3bd-d971-4070-997d-ba28fa394192'	System	24 Sep 2020 22:51:36
User entered 'Yes (Y)'	System	24 Sep 2020 22:51:36

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:27', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '67d0f3bd-d971-4070-997d-ba28fa394192' User entered '97.7'	System	24 Sep 2020 22:51:36
	System	24 Sep 2020 22:51:36

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:29', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '67d0f3bd-d971-4070-997d-ba28fa394192'	System	24 Sep 2020 22:51:36
User entered 'No (N)'	System	24 Sep 2020 22:51:36

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:32', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '67d0f3bd-d971-4070-997d-ba28fa394192' User entered '24 Sep 2020 17:51'	System	24 Sep 2020 22:51:36
	System	24 Sep 2020 22:51:36

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '24 Sep 2020 16:20'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 2'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:09:23', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5111118a-3957-4ae7-9958-b7309e814671' User entered 'Yes (Y)'	System	25 Sep 2020 17:10:07
	System	25 Sep 2020 17:10:07

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-25T12:09:27', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5111118a-3957-4ae7-9958-b7309e814671' User entered '97.5'	System	25 Sep 2020 17:10:07
	System	25 Sep 2020 17:10:07

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:09:30', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5111118a-3957-4ae7-9958-b7309e814671' User entered 'No (N)'	System	25 Sep 2020 17:10:07
	System	25 Sep 2020 17:10:07

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:09:33', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5111118a-3957-4ae7-9958-b7309e814671' User entered '25 Sep 2020 12:09'	System	25 Sep 2020 17:10:07
	System	25 Sep 2020 17:10:07

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 3'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:06', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '44f65fae-e497-44f1-96f7-c5e3fc615e1b'	System	27 Sep 2020 03:26:12
User entered 'No (N)'	System	27 Sep 2020 03:26:12

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:08', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '44f65fae-e497-44f1-96f7-c5e3fc615e1b'	System	27 Sep 2020 03:26:12
User entered 'No (N)'	System	27 Sep 2020 03:26:12

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-26T22:26:10', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '44f65fae-e497-44f1-96f7-c5e3fc615e1b' User entered '26 Sep 2020 22:26'	System	27 Sep 2020 03:26:12
	System	27 Sep 2020 03:26:12

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 4'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:00:30', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2fdc906a-865f-42e3-9130-71ade494ae22'	System	28 Sep 2020 06:00:37
User entered 'No (N)'	System	28 Sep 2020 06:00:37

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-28T01:00:32', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2fdc906a-865f-42e3-9130-71ade494ae22'	System	28 Sep 2020 06:00:37
User entered 'No (N)'	System	28 Sep 2020 06:00:37

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-28T01:00:34', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2fdc906a-865f-42e3-9130-71ade494ae22' User entered '28 Sep 2020 01:00'	System	28 Sep 2020 06:00:37
	System	28 Sep 2020 06:00:37

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 5'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T23:59:49', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '512bc17d-da7e-4b0a-bd78-b706e93a7a69' User entered 'No (N)'	System	29 Sep 2020 04:59:56
	System	29 Sep 2020 04:59:56

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T23:59:51', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '512bc17d-da7e-4b0a-bd78-b706e93a7a69' User entered 'No (N)'	System	29 Sep 2020 04:59:56
	System	29 Sep 2020 04:59:56

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T23:59:53', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '512bc17d-da7e-4b0a-bd78-b706e93a7a69' User entered '28 Sep 2020 23:59'	System	29 Sep 2020 04:59:56
	System	29 Sep 2020 04:59:56

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 6'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T00:18:57', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2789772a-f425-4106-839a-8b64590b1c48' User entered 'Yes (Y)'	System	30 Sep 2020 05:19:16
	System	30 Sep 2020 05:19:16

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T00:19:07', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2789772a-f425-4106-839a-8b64590b1c48' User entered '97.5'	System	30 Sep 2020 05:19:16
	System	30 Sep 2020 05:19:16

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T00:19:09', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2789772a-f425-4106-839a-8b64590b1c48' User entered 'No (N)'	System	30 Sep 2020 05:19:16
	System	30 Sep 2020 05:19:16

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T00:19:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2789772a-f425-4106-839a-8b64590b1c48' User entered '30 Sep 2020 00:19'	System	30 Sep 2020 05:19:16
	System	30 Sep 2020 05:19:16

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 7'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:02', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '72adac11-ceb0-4553-8398-b0dc3074dcce' User entered 'No (N)'	System	30 Sep 2020 19:19:08
	System	30 Sep 2020 19:19:08

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:05', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '72adac11-ceb0-4553-8398-b0dc3074dcce' User entered 'No (N)'	System	30 Sep 2020 19:19:08
	System	30 Sep 2020 19:19:08

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:07', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '72adac11-ceb0-4553-8398-b0dc3074dcce' User entered '30 Sep 2020 14:19'	System	30 Sep 2020 19:19:08
	System	30 Sep 2020 19:19:08

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:19', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3f132dcf-5d05-42ed-93f4-b5c14b378b20'	System	24 Sep 2020 18:13:34
User entered 'None (1)'	System	24 Sep 2020 18:13:34

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:22', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3f132dcf-5d05-42ed-93f4-b5c14b378b20'	System	24 Sep 2020 18:13:34
User entered 'No (N)'	System	24 Sep 2020 18:13:34

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:25', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3f132dcf-5d05-42ed-93f4-b5c14b378b20' User entered 'No (N)'	System	24 Sep 2020 18:13:34
	System	24 Sep 2020 18:13:34

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-24T13:13:27', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3f132dcf-5d05-42ed-93f4-b5c14b378b20'	System	24 Sep 2020 18:13:34
User entered 'None (1)'	System	24 Sep 2020 18:13:34

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:29', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '3f132dcf-5d05-42ed-93f4-b5c14b378b20' User entered '24 Sep 2020 13:13'	System	24 Sep 2020 18:13:34
	System	24 Sep 2020 18:13:34

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '24 Sep 2020 12:55'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '24 Sep 2020 15:25'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:35', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0b8c1992-da28-4f4d-a4ee-9a2f8ed1b644'	System	24 Sep 2020 22:51:48
User entered 'None (1)'	System	24 Sep 2020 22:51:48

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:37', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0b8c1992-da28-4f4d-a4ee-9a2f8ed1b644'	System	24 Sep 2020 22:51:48
User entered 'No (N)'	System	24 Sep 2020 22:51:48

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0b8c1992-da28-4f4d-a4ee-9a2f8ed1b644'	System	24 Sep 2020 22:51:48
User entered 'No (N)'	System	24 Sep 2020 22:51:48

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:41', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0b8c1992-da28-4f4d-a4ee-9a2f8ed1b644'	System	24 Sep 2020 22:51:48
User entered 'None (1)'	System	24 Sep 2020 22:51:48

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:44', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0b8c1992-da28-4f4d-a4ee-9a2f8ed1b644' User entered '24 Sep 2020 17:51'	System	24 Sep 2020 22:51:48
	System	24 Sep 2020 22:51:48

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '24 Sep 2020 16:20'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 2'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:09:37', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '41229c0f-5895-4f4f-a868-61e4b7eccc49'	System	25 Sep 2020 17:10:15
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 17:10:15

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:09:40', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '41229c0f-5895-4f4f-a868-61e4b7eccc49'	System	25 Sep 2020 17:10:15
User entered 'No (N)'	System	25 Sep 2020 17:10:15

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:09:51', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '41229c0f-5895-4f4f-a868-61e4b7eccc49'	System	25 Sep 2020 17:10:15
User entered 'No (N)'	System	25 Sep 2020 17:10:15

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:09:55', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '41229c0f-5895-4f4f-a868-61e4b7eccc49'	System	25 Sep 2020 17:10:15
User entered 'None (1)'	System	25 Sep 2020 17:10:15

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:09:59', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '41229c0f-5895-4f4f-a868-61e4b7eccc49' User entered '25 Sep 2020 12:09'	System	25 Sep 2020 17:10:15
	System	25 Sep 2020 17:10:15

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 3'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:14', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'fba0f14a-6a5d-45fa-a68a-bca3c1d5b47f'	System	27 Sep 2020 03:26:27
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 03:26:27

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:16', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'fba0f14a-6a5d-45fa-a68a-bca3c1d5b47f' User entered 'No (N)'	System	27 Sep 2020 03:26:27
	System	27 Sep 2020 03:26:27

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-26T22:26:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'fba0f14a-6a5d-45fa-a68a-bca3c1d5b47f' User entered 'No (N)'	System	27 Sep 2020 03:26:27
	System	27 Sep 2020 03:26:27

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-26T22:26:22', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'fba0f14a-6a5d-45fa-a68a-bca3c1d5b47f'	System	27 Sep 2020 03:26:27
User entered 'None (1)'	System	27 Sep 2020 03:26:27

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'fba0f14a-6a5d-45fa-a68a-bca3c1d5b47f' User entered '26 Sep 2020 22:26'	System	27 Sep 2020 03:26:27
	System	27 Sep 2020 03:26:27

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 4'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:00:43', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4ed40288-4aa1-4c6a-96ee-8149842d9d99'	System	28 Sep 2020 06:00:54
User entered 'None (1)'	System	28 Sep 2020 06:00:54

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-28T01:00:45', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4ed40288-4aa1-4c6a-96ee-8149842d9d99' User entered 'No (N)'	System	28 Sep 2020 06:00:54
	System	28 Sep 2020 06:00:54

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-28T01:00:48', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4ed40288-4aa1-4c6a-96ee-8149842d9d99'	System	28 Sep 2020 06:00:54
User entered 'No (N)'	System	28 Sep 2020 06:00:54

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-28T01:00:50', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4ed40288-4aa1-4c6a-96ee-8149842d9d99'	System	28 Sep 2020 06:00:54
User entered 'None (1)'	System	28 Sep 2020 06:00:54

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-28T01:00:52', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4ed40288-4aa1-4c6a-96ee-8149842d9d99' User entered '28 Sep 2020 01:00'	System	28 Sep 2020 06:00:54
	System	28 Sep 2020 06:00:54

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 5'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T23:59:58', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0fb88deb-5691-4fd7-ae6b-d7f290a78752'	System	29 Sep 2020 05:00:11
User entered 'None (1)'	System	29 Sep 2020 05:00:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-29T00:00:01', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0fb88deb-5691-4fd7-ae6b-d7f290a78752'	System	29 Sep 2020 05:00:11
User entered 'No (N)'	System	29 Sep 2020 05:00:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-29T00:00:04', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0fb88deb-5691-4fd7-ae6b-d7f290a78752'	System	29 Sep 2020 05:00:11
User entered 'No (N)'	System	29 Sep 2020 05:00:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-29T00:00:07', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0fb88deb-5691-4fd7-ae6b-d7f290a78752'	System	29 Sep 2020 05:00:11
User entered 'None (1)'	System	29 Sep 2020 05:00:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-29T00:00:09', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0fb88deb-5691-4fd7-ae6b-d7f290a78752'	System	29 Sep 2020 05:00:11
User entered '29 Sep 2020 00:00'	System	29 Sep 2020 05:00:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 6'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T00:19:17', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4bdec97b-664d-4d7a-8ed2-ba894fcf8581'	System	30 Sep 2020 05:19:31
User entered 'None (1)'	System	30 Sep 2020 05:19:31

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T00:19:20', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4bdec97b-664d-4d7a-8ed2-ba894fcf8581'	System	30 Sep 2020 05:19:31
User entered 'No (N)'	System	30 Sep 2020 05:19:31

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:22', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4bdec97b-664d-4d7a-8ed2-ba894fcf8581'	System	30 Sep 2020 05:19:31
User entered 'No (N)'	System	30 Sep 2020 05:19:31

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T00:19:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4bdec97b-664d-4d7a-8ed2-ba894fcf8581'	System	30 Sep 2020 05:19:31
User entered 'None (1)'	System	30 Sep 2020 05:19:31

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T00:19:26', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '4bdec97b-664d-4d7a-8ed2-ba894fcf8581' User entered '30 Sep 2020 00:19'	System	30 Sep 2020 05:19:31
	System	30 Sep 2020 05:19:31

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 7'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:10', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'baac5344-90c8-4868-97f3-3c386ebf0c09'	System	30 Sep 2020 19:19:21
User entered 'None (1)'	System	30 Sep 2020 19:19:21

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:12', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'baac5344-90c8-4868-97f3-3c386ebf0c09'	System	30 Sep 2020 19:19:21
User entered 'No (N)'	System	30 Sep 2020 19:19:21

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:14', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'baac5344-90c8-4868-97f3-3c386ebf0c09'	System	30 Sep 2020 19:19:21
User entered 'No (N)'	System	30 Sep 2020 19:19:21

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T14:19:16', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'baac5344-90c8-4868-97f3-3c386ebf0c09'	System	30 Sep 2020 19:19:21
User entered 'None (1)'	System	30 Sep 2020 19:19:21

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-30T14:19:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'baac5344-90c8-4868-97f3-3c386ebf0c09' User entered '30 Sep 2020 14:19'	System	30 Sep 2020 19:19:21
	System	30 Sep 2020 19:19:21

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:33', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '30201dd1-4df1-4b26-a1da-0ee73b5075fd' User entered 'None (0)'	System	24 Sep 2020 18:13:51
	System	24 Sep 2020 18:13:51

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '30201dd1-4df1-4b26-a1da-0ee73b5075fd' User entered 'None (0)'	System	24 Sep 2020 18:13:51
	System	24 Sep 2020 18:13:51

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:38', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '30201dd1-4df1-4b26-a1da-0ee73b5075fd' User entered 'None (0)'	System	24 Sep 2020 18:13:51
	System	24 Sep 2020 18:13:51

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:40', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '30201dd1-4df1-4b26-a1da-0ee73b5075fd' User entered 'None (0)'	System	24 Sep 2020 18:13:51
	System	24 Sep 2020 18:13:51

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:42', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '30201dd1-4df1-4b26-a1da-0ee73b5075fd' User entered 'None (0)'	System	24 Sep 2020 18:13:51
	System	24 Sep 2020 18:13:51

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-24T13:13:44', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '30201dd1-4df1-4b26-a1da-0ee73b5075fd' User entered 'None (0)'	System	24 Sep 2020 18:13:51
	System	24 Sep 2020 18:13:51

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:45', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '30201dd1-4df1-4b26-a1da-0ee73b5075fd' User entered 'No (N)'	System	24 Sep 2020 18:13:51
	System	24 Sep 2020 18:13:51

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T13:13:47', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '30201dd1-4df1-4b26-a1da-0ee73b5075fd' User entered '24 Sep 2020 13:13'	System	24 Sep 2020 18:13:51
	System	24 Sep 2020 18:13:51

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Sep 2020 12:55'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Sep 2020 15:25'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:47', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '259bd581-b274-4ce3-bdcc-ad45203461e7' User entered 'None (0)'	System	24 Sep 2020 22:52:04
	System	24 Sep 2020 22:52:04

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:49', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '259bd581-b274-4ce3-bdcc-ad45203461e7' User entered 'None (0)'	System	24 Sep 2020 22:52:04
	System	24 Sep 2020 22:52:04

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:51', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '259bd581-b274-4ce3-bdcc-ad45203461e7' User entered 'None (0)'	System	24 Sep 2020 22:52:04
	System	24 Sep 2020 22:52:04

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:53', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '259bd581-b274-4ce3-bdcc-ad45203461e7' User entered 'None (0)'	System	24 Sep 2020 22:52:04
	System	24 Sep 2020 22:52:04

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:55', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '259bd581-b274-4ce3-bdcc-ad45203461e7' User entered 'None (0)'	System	24 Sep 2020 22:52:04
	System	24 Sep 2020 22:52:04

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:57', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '259bd581-b274-4ce3-bdcc-ad45203461e7' User entered 'None (0)'	System	24 Sep 2020 22:52:04
	System	24 Sep 2020 22:52:04

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-24T17:51:59', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '259bd581-b274-4ce3-bdcc-ad45203461e7' User entered 'No (N)'	System	24 Sep 2020 22:52:04
	System	24 Sep 2020 22:52:04

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-09-24T17:52:01', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '259bd581-b274-4ce3-bdcc-ad45203461e7' User entered '24 Sep 2020 17:52'	System	24 Sep 2020 22:52:04
	System	24 Sep 2020 22:52:04

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '24 Sep 2020 16:20'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 2'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:10:03', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1bbcf2d9-b95d-402f-add8-826f493c90b2' User entered 'None (0)'	System	25 Sep 2020 17:10:25
	System	25 Sep 2020 17:10:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:10:05', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1bbcf2d9-b95d-402f-add8-826f493c90b2' User entered 'None (0)'	System	25 Sep 2020 17:10:25
	System	25 Sep 2020 17:10:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:10:08', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1bbcf2d9-b95d-402f-add8-826f493c90b2'	System	25 Sep 2020 17:10:25
User entered 'No interference with activity (1)'	System	25 Sep 2020 17:10:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:10:11', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1bbcf2d9-b95d-402f-add8-826f493c90b2' User entered 'None (0)'	System	25 Sep 2020 17:10:25
	System	25 Sep 2020 17:10:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:10:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1bbcf2d9-b95d-402f-add8-826f493c90b2' User entered 'None (0)'	System	25 Sep 2020 17:10:25
	System	25 Sep 2020 17:10:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:10:15', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1bbcf2d9-b95d-402f-add8-826f493c90b2' User entered 'None (0)'	System	25 Sep 2020 17:10:25
	System	25 Sep 2020 17:10:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:10:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1bbcf2d9-b95d-402f-add8-826f493c90b2' User entered 'No (N)'	System	25 Sep 2020 17:10:25
	System	25 Sep 2020 17:10:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-25T12:10:20', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1bbcf2d9-b95d-402f-add8-826f493c90b2' User entered '25 Sep 2020 12:10'	System	25 Sep 2020 17:10:25
	System	25 Sep 2020 17:10:25

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 3'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:28', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1d46ac65-2e9f-4ba4-99f3-5786f3828335' User entered 'None (0)'	System	27 Sep 2020 03:26:48
	System	27 Sep 2020 03:26:48

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:32', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1d46ac65-2e9f-4ba4-99f3-5786f3828335' User entered 'None (0)'	System	27 Sep 2020 03:26:48
	System	27 Sep 2020 03:26:48

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:34', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1d46ac65-2e9f-4ba4-99f3-5786f3828335'	System	27 Sep 2020 03:26:48
User entered 'None (0)'	System	27 Sep 2020 03:26:48

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1d46ac65-2e9f-4ba4-99f3-5786f3828335' User entered 'None (0)'	System	27 Sep 2020 03:26:48
	System	27 Sep 2020 03:26:48

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:38', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1d46ac65-2e9f-4ba4-99f3-5786f3828335' User entered 'None (0)'	System	27 Sep 2020 03:26:48
	System	27 Sep 2020 03:26:48

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:41', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1d46ac65-2e9f-4ba4-99f3-5786f3828335' User entered 'None (0)'	System	27 Sep 2020 03:26:48
	System	27 Sep 2020 03:26:48

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:43', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1d46ac65-2e9f-4ba4-99f3-5786f3828335'	System	27 Sep 2020 03:26:48
User entered 'No (N)'	System	27 Sep 2020 03:26:48

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-26T22:26:45', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1d46ac65-2e9f-4ba4-99f3-5786f3828335' User entered '26 Sep 2020 22:26'	System	27 Sep 2020 03:26:48
	System	27 Sep 2020 03:26:48

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 4'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:00:55', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1b6ca994-820f-470f-8ce7-a13b6a9c6d46' User entered 'None (0)'	System	28 Sep 2020 06:01:16
	System	28 Sep 2020 06:01:16

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:00:58', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1b6ca994-820f-470f-8ce7-a13b6a9c6d46' User entered 'None (0)'	System	28 Sep 2020 06:01:16
	System	28 Sep 2020 06:01:16

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:01:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1b6ca994-820f-470f-8ce7-a13b6a9c6d46' User entered 'None (0)'	System	28 Sep 2020 06:01:16
	System	28 Sep 2020 06:01:16

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:01:04', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1b6ca994-820f-470f-8ce7-a13b6a9c6d46'	System	28 Sep 2020 06:01:16
User entered 'Some interference with activity (2)'	System	28 Sep 2020 06:01:16

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:01:06', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1b6ca994-820f-470f-8ce7-a13b6a9c6d46' User entered 'None (0)'	System	28 Sep 2020 06:01:16
	System	28 Sep 2020 06:01:16

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:01:08', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1b6ca994-820f-470f-8ce7-a13b6a9c6d46' User entered 'None (0)'	System	28 Sep 2020 06:01:16
	System	28 Sep 2020 06:01:16

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:01:11', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1b6ca994-820f-470f-8ce7-a13b6a9c6d46'	System	28 Sep 2020 06:01:16
User entered 'No (N)'	System	28 Sep 2020 06:01:16

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-28T01:01:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '1b6ca994-820f-470f-8ce7-a13b6a9c6d46' User entered '28 Sep 2020 01:01'	System	28 Sep 2020 06:01:16
	System	28 Sep 2020 06:01:16

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 5'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-29T00:00:12', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6c14b887-f81c-42fe-a9b9-15d1bee3e860' User entered 'None (0)'	System	29 Sep 2020 05:00:24
	System	29 Sep 2020 05:00:24

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-29T00:00:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6c14b887-f81c-42fe-a9b9-15d1bee3e860' User entered 'None (0)'	System	29 Sep 2020 05:00:24
	System	29 Sep 2020 05:00:24

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-29T00:00:15', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6c14b887-f81c-42fe-a9b9-15d1bee3e860' User entered 'None (0)'	System	29 Sep 2020 05:00:24
	System	29 Sep 2020 05:00:24

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-29T00:00:17', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6c14b887-f81c-42fe-a9b9-15d1bee3e860' User entered 'None (0)'	System	29 Sep 2020 05:00:24
	System	29 Sep 2020 05:00:24

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-29T00:00:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6c14b887-f81c-42fe-a9b9-15d1bee3e860' User entered 'None (0)'	System	29 Sep 2020 05:00:24
	System	29 Sep 2020 05:00:24

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-29T00:00:19', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6c14b887-f81c-42fe-a9b9-15d1bee3e860'	System	29 Sep 2020 05:00:24
User entered 'None (0)'	System	29 Sep 2020 05:00:24

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-29T00:00:20', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6c14b887-f81c-42fe-a9b9-15d1bee3e860' User entered 'No (N)'	System	29 Sep 2020 05:00:24
	System	29 Sep 2020 05:00:24

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-29T00:00:22', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '6c14b887-f81c-42fe-a9b9-15d1bee3e860' User entered '29 Sep 2020 00:00'	System	29 Sep 2020 05:00:24
	System	29 Sep 2020 05:00:24

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 6'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:29', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '866414c0-c0ef-4f0f-b41d-6296ff3b8753'	System	30 Sep 2020 05:19:46
User entered 'None (0)'	System	30 Sep 2020 05:19:46

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:31', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '866414c0-c0ef-4f0f-b41d-6296ff3b8753' User entered 'None (0)'	System	30 Sep 2020 05:19:46
	System	30 Sep 2020 05:19:46

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:33', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '866414c0-c0ef-4f0f-b41d-6296ff3b8753' User entered 'None (0)'	System	30 Sep 2020 05:19:46
	System	30 Sep 2020 05:19:46

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:35', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '866414c0-c0ef-4f0f-b41d-6296ff3b8753' User entered 'None (0)'	System	30 Sep 2020 05:19:46
	System	30 Sep 2020 05:19:46

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '866414c0-c0ef-4f0f-b41d-6296ff3b8753'	System	30 Sep 2020 05:19:46
User entered 'None (0)'	System	30 Sep 2020 05:19:46

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '866414c0-c0ef-4f0f-b41d-6296ff3b8753' User entered 'None (0)'	System	30 Sep 2020 05:19:46
	System	30 Sep 2020 05:19:46

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:41', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '866414c0-c0ef-4f0f-b41d-6296ff3b8753' User entered 'No (N)'	System	30 Sep 2020 05:19:46
	System	30 Sep 2020 05:19:46

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T00:19:43', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '866414c0-c0ef-4f0f-b41d-6296ff3b8753'	System	30 Sep 2020 05:19:46
User entered '30 Sep 2020 00:19'	System	30 Sep 2020 05:19:46

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
Data entry locked.	System	24 Sep 2020 17:59:11
User entered 'Day 7'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:22', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e4cd8a6-b45b-40c6-8bc8-93dd6aa1e933' User entered 'None (0)'	System	30 Sep 2020 19:19:44
	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:23', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e4cd8a6-b45b-40c6-8bc8-93dd6aa1e933' User entered 'None (0)'	System	30 Sep 2020 19:19:44
	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:25', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e4cd8a6-b45b-40c6-8bc8-93dd6aa1e933' User entered 'None (0)'	System	30 Sep 2020 19:19:44
	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:28', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e4cd8a6-b45b-40c6-8bc8-93dd6aa1e933' User entered 'None (0)'	System	30 Sep 2020 19:19:44
	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:34', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e4cd8a6-b45b-40c6-8bc8-93dd6aa1e933'	System	30 Sep 2020 19:19:44
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e4cd8a6-b45b-40c6-8bc8-93dd6aa1e933'	System	30 Sep 2020 19:19:44
User entered 'None (0)'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e4cd8a6-b45b-40c6-8bc8-93dd6aa1e933'	System	30 Sep 2020 19:19:44
User entered 'No (N)'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-09-30T14:19:41', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '0e4cd8a6-b45b-40c6-8bc8-93dd6aa1e933'	System	30 Sep 2020 19:19:44
User entered '30 Sep 2020 14:19'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:45
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:59:11

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	30 Sep 2020 19:19:44
User entered 'Day 8'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:54:53

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	30 Sep 2020 19:19:44
User entered 'Day 9'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 14:54:53

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	30 Sep 2020 19:19:44
User entered 'Day 8'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	30 Sep 2020 19:19:44
User entered 'Day 9'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:54:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:19:44

US3032323

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:19:44

US3032323

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:10:24
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	01 Oct 2020 16:57:47

US3032323

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:10:24
User entered '01 Oct 2020'	(b) (4) Samantha Wieseler (b) (4)	01 Oct 2020 16:57:47

US3032323

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:10:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	01 Oct 2020 16:57:47

US3032323

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:10:24
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	01 Oct 2020 16:57:47
	(b) (4)	

US3032323

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:10:24
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	01 Oct 2020 16:57:57

US3032323

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	01 Oct 2020 16:57:57

US3032323

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 16:48:36

US3032323

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
User entered '8 Oct 2020'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 16:48:36
	(b) (4)	

US3032323

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 16:48:36

US3032323

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
User entered empty.	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 16:48:36
	(b) (4)	

US3032323

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:10:28
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 16:48:39

US3032323

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	08 Oct 2020 16:48:39

US3032323

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	15 Oct 2020 15:26:04

US3032323

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '15 Oct 2020'	(b) (4) Samantha Wieseler (b) (4)	15 Oct 2020 15:26:04

US3032323

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	15 Oct 2020 15:26:04

US3032323

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	15 Oct 2020 15:26:04
	(b) (4)	

US3032323

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	15 Oct 2020 15:26:08

US3032323

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	15 Oct 2020 15:26:08

US3032323

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:19:47
	(b) (4)	

US3032323

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:19:47
	(b) (4)	

US3032323

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:19:47

US3032323

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'VISIT3'	System	19 Oct 2020 19:19:47

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16
	(b) (4)	

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '13:53'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '19 Oct 2020 13:53'	System	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16
	(b) (4)	

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '70'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'bpm'	System	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'breaths/min'	System	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '103'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '79'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'mmHg'	System	19 Oct 2020 19:21:16

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20

US3032323

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20

US3032323

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:23

US3032323

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:23
	(b) (4)	

US3032323

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:31

US3032323

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:31
	(b) (4)	

US3032323

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered '14:09'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:31
	(b) (4)	

US3032323

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '19 Oct 2020 14:09'	System	19 Oct 2020 19:21:31

US3032323

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:41
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 19:21:33

US3032323

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered '1'	System	19 Oct 2020 19:21:33

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 64'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-10-22T00:01:12', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '022341df-e789-47fb-8068-68e05afd15e0'	System	22 Oct 2020 05:01:23
User entered 'No (N)'	System	22 Oct 2020 05:01:23

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-10-22T00:01:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '022341df-e789-47fb-8068-68e05afd15e0' User entered 'No (N)'	System	22 Oct 2020 05:01:23
	System	22 Oct 2020 05:01:23

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-10-22T00:01:21', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '022341df-e789-47fb-8068-68e05afd15e0' User entered '22 Oct 2020 00:01:21'	System	22 Oct 2020 05:01:23
	System	22 Oct 2020 05:01:23

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 71'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-10-29T00:46:20', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'b26cb059-3996-4311-8fa3-c2ff129983a2'	System	29 Oct 2020 05:46:29
User entered 'No (N)'	System	29 Oct 2020 05:46:29

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-10-29T00:46:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'b26cb059-3996-4311-8fa3-c2ff129983a2'	System	29 Oct 2020 05:46:29
User entered 'No (N)'	System	29 Oct 2020 05:46:29

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-10-29T00:46:27', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'b26cb059-3996-4311-8fa3-c2ff129983a2' User entered '29 Oct 2020 00:46:27'	System	29 Oct 2020 05:46:29
	System	29 Oct 2020 05:46:29

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 78'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-11-05T00:02:51', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '28309941-c993-410a-bedc-f40a56677307'	System	05 Nov 2020 06:03:06
User entered 'No (N)'	System	05 Nov 2020 06:03:06

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-11-05T00:03:01', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '28309941-c993-410a-bedc-f40a56677307'	System	05 Nov 2020 06:03:06
User entered 'No (N)'	System	05 Nov 2020 06:03:06

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-11-05T00:03:04', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '28309941-c993-410a-bedc-f40a56677307' User entered '05 Nov 2020 00:03:04'	System	05 Nov 2020 06:03:06
	System	05 Nov 2020 06:03:06

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered 'Day 92'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-11-19T00:01:16', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'bee31bf8-dec2-45f0-b16d-698ce6515e6'	System	19 Nov 2020 06:01:37
User entered 'Yes (Y)'	System	19 Nov 2020 06:01:37

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-11-19T00:01:20', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'bee31bf8-dec2-45f0-b16d-698ce6515e6'	System	19 Nov 2020 06:01:37
User entered 'No (N)'	System	19 Nov 2020 06:01:37

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-11-19T00:01:24', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'bee31bf8-dec2-45f0-b16d-698ce6515e6'	System	19 Nov 2020 06:01:37
User entered 'No (N)'	System	19 Nov 2020 06:01:37

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-BOCC-8D834C8E4679)', Time: '2020-11-19T00:01:28', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'bee31bf8-dec2-45f0-b16d-698ce6515e6'	System	19 Nov 2020 06:01:37
User entered 'No (N)'	System	19 Nov 2020 06:01:37

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-11-19T00:01:33', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'bee31bf8-dec2-45f0-b16d-698ce6515e6e' User entered '19 Nov 2020 00:01:33'	System	19 Nov 2020 06:01:37
	System	19 Nov 2020 06:01:37

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 19:44:13

US3032323

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:56
Data entry locked.	System	22 Aug 2020 19:44:13
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 19:44:13

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-11-26T00:06:54', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'eb6e0a27-e97d-4db2-ba4d-246a264136d6'	System	26 Nov 2020 06:07:03
User entered 'No (N)'	System	26 Nov 2020 06:07:03

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-11-26T00:06:56', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'eb6e0a27-e97d-4db2-ba4d-246a264136d6'	System	26 Nov 2020 06:07:03
User entered 'No (N)'	System	26 Nov 2020 06:07:03

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-11-26T00:07:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'eb6e0a27-e97d-4db2-ba4d-246a264136d6' User entered '26 Nov 2020 00:07:00'	System	26 Nov 2020 06:07:03
	System	26 Nov 2020 06:07:03

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-11-30T00:05:54', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'ab709b5f-b21b-48e4-8d13-caa71c0f708d'	System	30 Nov 2020 06:06:01
User entered 'No (N)'	System	30 Nov 2020 06:06:01

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-11-30T00:05:56', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'ab709b5f-b21b-48e4-8d13-caa71c0f708d'	System	30 Nov 2020 06:06:01
User entered 'No (N)'	System	30 Nov 2020 06:06:01

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-11-30T00:05:59', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'ab709b5f-b21b-48e4-8d13-caa71c0f708d' User entered '30 Nov 2020 00:05:59'	System	30 Nov 2020 06:06:01
	System	30 Nov 2020 06:06:01

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-07T01:26:21', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '27f745bc-776a-4456-ae6a-a5e8cf848abd'	System	07 Dec 2020 07:26:30
User entered 'No (N)'	System	07 Dec 2020 07:26:30

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-07T01:26:23', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '27f745bc-776a-4456-ae6a-a5e8cf848abd'	System	07 Dec 2020 07:26:30
User entered 'No (N)'	System	07 Dec 2020 07:26:30

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-07T01:26:26', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '27f745bc-776a-4456-ae6a-a5e8cf848abd' User entered '07 Dec 2020 01:26:26'	System	07 Dec 2020 07:26:30
	System	07 Dec 2020 07:26:30

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-14T00:47:11', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '852a445f-a362-4411-81c9-006181027f54'	System	14 Dec 2020 06:47:21
User entered 'No (N)'	System	14 Dec 2020 06:47:21

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-14T00:47:16', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '852a445f-a362-4411-81c9-006181027f54'	System	14 Dec 2020 06:47:21
User entered 'No (N)'	System	14 Dec 2020 06:47:21

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-14T00:47:19', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '852a445f-a362-4411-81c9-006181027f54' User entered '14 Dec 2020 00:47:19'	System	14 Dec 2020 06:47:21
	System	14 Dec 2020 06:47:21

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-21T00:33:31', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5c8ff9ad-3129-49f3-b018-7d202de2fc6e'	System	21 Dec 2020 06:33:39
User entered 'No (N)'	System	21 Dec 2020 06:33:39

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-21T00:33:33', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5c8ff9ad-3129-49f3-b018-7d202de2fc6e'	System	21 Dec 2020 06:33:39
User entered 'No (N)'	System	21 Dec 2020 06:33:39

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-21T00:33:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5c8ff9ad-3129-49f3-b018-7d202de2fc6e' User entered '21 Dec 2020 00:33:36'	System	21 Dec 2020 06:33:39
	System	21 Dec 2020 06:33:39

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-28T00:01:14', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '7f2278b9-6434-40c1-9652-414dac41123b'	System	28 Dec 2020 06:01:23
User entered 'No (N)'	System	28 Dec 2020 06:01:23

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-28T00:01:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '7f2278b9-6434-40c1-9652-414dac41123b'	System	28 Dec 2020 06:01:23
User entered 'No (N)'	System	28 Dec 2020 06:01:23

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2020-12-28T00:01:21', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '7f2278b9-6434-40c1-9652-414dac41123b'	System	28 Dec 2020 06:01:23
User entered '28 Dec 2020 00:01:21'	System	28 Dec 2020 06:01:23

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-04T04:54:37', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8c7f07d2-c6c0-4dc2-9f0d-d439d3d83ee8'	System	04 Jan 2021 10:54:46
User entered 'No (N)'	System	04 Jan 2021 10:54:46

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-04T04:54:40', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8c7f07d2-c6c0-4dc2-9f0d-d439d3d83ee8'	System	04 Jan 2021 10:54:46
User entered 'No (N)'	System	04 Jan 2021 10:54:46

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-04T04:54:42', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8c7f07d2-c6c0-4dc2-9f0d-d439d3d83ee8' User entered '04 Jan 2021 04:54:42'	System	04 Jan 2021 10:54:46
	System	04 Jan 2021 10:54:46

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-11T02:54:05', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '54d30e81-35dd-41e3-9b8e-b251210b158b'	System	11 Jan 2021 08:54:18
User entered 'No (N)'	System	11 Jan 2021 08:54:18

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-11T02:54:12', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '54d30e81-35dd-41e3-9b8e-b251210b158b'	System	11 Jan 2021 08:54:18
User entered 'No (N)'	System	11 Jan 2021 08:54:18

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-11T02:54:15', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '54d30e81-35dd-41e3-9b8e-b251210b158b' User entered '11 Jan 2021 02:54:15'	System	11 Jan 2021 08:54:18
	System	11 Jan 2021 08:54:18

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-18T00:11:14', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2ec97e62-e32a-4f2b-9392-75e34cce3817'	System	18 Jan 2021 06:11:27
User entered 'No (N)'	System	18 Jan 2021 06:11:27

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-18T00:11:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2ec97e62-e32a-4f2b-9392-75e34cce3817'	System	18 Jan 2021 06:11:27
User entered 'No (N)'	System	18 Jan 2021 06:11:27

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-18T00:11:20', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '2ec97e62-e32a-4f2b-9392-75e34cce3817' User entered '18 Jan 2021 00:11:20'	System	18 Jan 2021 06:11:27
	System	18 Jan 2021 06:11:27

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-25T11:07:10', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'dc181ea2-ee58-4b1f-b101-3f09261458fe'	System	25 Jan 2021 17:09:08
User entered 'Yes (Y)'	System	25 Jan 2021 17:09:08

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-25T11:07:13', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'dc181ea2-ee58-4b1f-b101-3f09261458fe'	System	25 Jan 2021 17:09:08
User entered 'No (N)'	System	25 Jan 2021 17:09:08

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-25T11:07:18', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'dc181ea2-ee58-4b1f-b101-3f09261458fe'	System	25 Jan 2021 17:09:08
User entered 'No (N)'	System	25 Jan 2021 17:09:08

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-25T11:07:48', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'dc181ea2-ee58-4b1f-b101-3f09261458fe'	System	25 Jan 2021 17:09:08
User entered 'No (N)'	System	25 Jan 2021 17:09:08

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-01-25T11:08:03', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'dc181ea2-ee58-4b1f-b101-3f09261458fe' User entered '25 Jan 2021 11:08:03'	System	25 Jan 2021 17:09:08
	System	25 Jan 2021 17:09:08

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-01T00:39:34', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a72cfb2d-a305-437a-b7b9-d2a58b8c53b6'	System	01 Feb 2021 06:39:57
User entered 'Yes (Y)'	System	01 Feb 2021 06:39:57

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-01T00:39:36', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a72cfb2d-a305-437a-b7b9-d2a58b8c53b6'	System	01 Feb 2021 06:39:57
User entered 'No (N)'	System	01 Feb 2021 06:39:57

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-01T00:39:39', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a72cfb2d-a305-437a-b7b9-d2a58b8c53b6'	System	01 Feb 2021 06:39:57
User entered 'No (N)'	System	01 Feb 2021 06:39:57

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-01T00:39:49', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a72cfb2d-a305-437a-b7b9-d2a58b8c53b6'	System	01 Feb 2021 06:39:57
User entered 'No (N)'	System	01 Feb 2021 06:39:57

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-01T00:39:51', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a72cfb2d-a305-437a-b7b9-d2a58b8c53b6' User entered '01 Feb 2021 00:39:51'	System	01 Feb 2021 06:39:57
	System	01 Feb 2021 06:39:57

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-08T00:01:49', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '99fc8d83-36a2-4d2e-aafb-c75ca3a0dd4c'	System	08 Feb 2021 06:02:05
User entered 'Yes (Y)'	System	08 Feb 2021 06:02:05

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-08T00:01:52', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '99fc8d83-36a2-4d2e-aafb-c75ca3a0dd4c'	System	08 Feb 2021 06:02:05
User entered 'No (N)'	System	08 Feb 2021 06:02:05

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-08T00:01:54', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '99fc8d83-36a2-4d2e-aafb-c75ca3a0dd4c'	System	08 Feb 2021 06:02:05
User entered 'No (N)'	System	08 Feb 2021 06:02:05

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-08T00:01:59', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '99fc8d83-36a2-4d2e-aafb-c75ca3a0dd4c'	System	08 Feb 2021 06:02:05
User entered 'No (N)'	System	08 Feb 2021 06:02:05

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-08T00:02:02', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '99fc8d83-36a2-4d2e-aafb-c75ca3a0dd4c'	System	08 Feb 2021 06:02:05
User entered '08 Feb 2021 00:02:02'	System	08 Feb 2021 06:02:05

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-15T08:15:46', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5a3bdd07-91b0-428c-ad97-d3dabe7ecdc4'	System	15 Feb 2021 14:15:57
User entered 'No (N)'	System	15 Feb 2021 14:15:57

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-15T08:15:50', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5a3bdd07-91b0-428c-ad97-d3dabe7ecdc4'	System	15 Feb 2021 14:15:57
User entered 'No (N)'	System	15 Feb 2021 14:15:57

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-15T08:15:54', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '5a3bdd07-91b0-428c-ad97-d3dabe7ecdc4'	System	15 Feb 2021 14:15:57
User entered '15 Feb 2021 08:15:54'	System	15 Feb 2021 14:15:57

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-22T10:29:03', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '746be2a2-3c63-4e16-81dd-5ddd6373ce44'	System	22 Feb 2021 16:29:13
User entered 'No (N)'	System	22 Feb 2021 16:29:13

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-22T10:29:06', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '746be2a2-3c63-4e16-81dd-5ddd6373ce44'	System	22 Feb 2021 16:29:13
User entered 'No (N)'	System	22 Feb 2021 16:29:13

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-02-22T10:29:09', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '746be2a2-3c63-4e16-81dd-5ddd6373ce44'	System	22 Feb 2021 16:29:13
User entered '22 Feb 2021 10:29:09'	System	22 Feb 2021 16:29:13

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-01T00:03:14-06:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '72b34162-887d-4226-aa31-0e62cfe80262'	System	01 Mar 2021 06:03:29
User entered 'No (N)'	System	01 Mar 2021 06:03:29

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-01T00:03:16-06:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '72b34162-887d-4226-aa31-0e62cfe80262'	System	01 Mar 2021 06:03:29
User entered 'No (N)'	System	01 Mar 2021 06:03:29

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-01T00:03:18-06:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '72b34162-887d-4226-aa31-0e62cfe80262'	System	01 Mar 2021 06:03:29
User entered '01 Mar 2021 06:03:18'	System	01 Mar 2021 06:03:29

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-08T00:02:24-06:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'fd5b278b-abce-4c04-a39c-73998b622d53'	System	08 Mar 2021 06:02:30
User entered 'No (N)'	System	08 Mar 2021 06:02:30

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-08T00:02:25-06:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'fd5b278b-abce-4c04-a39c-73998b622d53'	System	08 Mar 2021 06:02:30
User entered 'No (N)'	System	08 Mar 2021 06:02:30

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-08T00:02:28-06:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'fd5b278b-abce-4c04-a39c-73998b622d53'	System	08 Mar 2021 06:02:30
User entered '08 Mar 2021 06:02:28'	System	08 Mar 2021 06:02:30

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-15T00:04:15-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e0ca791a-7ead-4f42-83a6-59d962ec2233'	System	15 Mar 2021 05:04:27
User entered 'No (N)'	System	15 Mar 2021 05:04:27

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-15T00:04:17-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e0ca791a-7ead-4f42-83a6-59d962ec2233'	System	15 Mar 2021 05:04:27
User entered 'No (N)'	System	15 Mar 2021 05:04:27

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-15T00:04:21-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'e0ca791a-7ead-4f42-83a6-59d962ec2233'	System	15 Mar 2021 05:04:27
User entered '15 Mar 2021 05:04:21'	System	15 Mar 2021 05:04:27

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-22T00:39:03-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'f3f0ed17-cfa8-4946-a24e-2509a6150328'	System	22 Mar 2021 05:39:12
User entered 'No (N)'	System	22 Mar 2021 05:39:12

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-22T00:39:05-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'f3f0ed17-cfa8-4946-a24e-2509a6150328'	System	22 Mar 2021 05:39:12
User entered 'No (N)'	System	22 Mar 2021 05:39:12

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-22T00:39:08-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'f3f0ed17-cfa8-4946-a24e-2509a6150328'	System	22 Mar 2021 05:39:12
User entered '22 Mar 2021 05:39:08'	System	22 Mar 2021 05:39:12

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-29T00:02:47-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '773536f0-e23a-47d1-8104-1f5bd19761cf'	System	07 Apr 2021 17:05:23
User entered 'No (N)'	System	07 Apr 2021 17:05:23

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-29T00:02:49-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '773536f0-e23a-47d1-8104-1f5bd19761cf'	System	07 Apr 2021 17:05:23
User entered 'No (N)'	System	07 Apr 2021 17:05:23

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-29T00:02:51-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '773536f0-e23a-47d1-8104-1f5bd19761cf'	System	07 Apr 2021 17:05:23
User entered '29 Mar 2021 05:02:51'	System	07 Apr 2021 17:05:23

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-07T12:00:16-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '9343d221-27c9-49e2-b713-e5c520d068cf'	System	07 Apr 2021 17:05:39
User entered 'No (N)'	System	07 Apr 2021 17:05:39

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-07T12:00:18-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '9343d221-27c9-49e2-b713-e5c520d068cf'	System	07 Apr 2021 17:05:39
User entered 'No (N)'	System	07 Apr 2021 17:05:39

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-07T12:00:20-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '9343d221-27c9-49e2-b713-e5c520d068cf'	System	07 Apr 2021 17:05:39
User entered '07 Apr 2021 17:00:20'	System	07 Apr 2021 17:05:39

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-12T06:32:08-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '856a672d-687b-428f-a32d-628233857d81'	System	12 Apr 2021 11:32:34
User entered 'No (N)'	System	12 Apr 2021 11:32:34

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-12T06:32:10-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '856a672d-687b-428f-a32d-628233857d81'	System	12 Apr 2021 11:32:34
User entered 'No (N)'	System	12 Apr 2021 11:32:34

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-12T06:32:13-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '856a672d-687b-428f-a32d-628233857d81'	System	12 Apr 2021 11:32:34
User entered '12 Apr 2021 11:32:13'	System	12 Apr 2021 11:32:34

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-19T09:20:01-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'd7986eb9-597e-49af-9a7a-386a650c5ae8'	System	19 Apr 2021 14:20:14
User entered 'No (N)'	System	19 Apr 2021 14:20:14

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-19T09:20:03-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'd7986eb9-597e-49af-9a7a-386a650c5ae8'	System	19 Apr 2021 14:20:14
User entered 'No (N)'	System	19 Apr 2021 14:20:14

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-19T09:20:05-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'd7986eb9-597e-49af-9a7a-386a650c5ae8'	System	19 Apr 2021 14:20:14
User entered '19 Apr 2021 14:20:05'	System	19 Apr 2021 14:20:14

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-26T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a68a650b-060d-4f18-ac33-03a4197f4d70'	System	26 Apr 2021 05:02:42
User entered 'No (N)'	System	26 Apr 2021 05:02:42

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-26T00:02:37-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a68a650b-060d-4f18-ac33-03a4197f4d70'	System	26 Apr 2021 05:02:42
User entered 'No (N)'	System	26 Apr 2021 05:02:42

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-04-26T00:02:40-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: 'a68a650b-060d-4f18-ac33-03a4197f4d70'	System	26 Apr 2021 05:02:42
User entered '26 Apr 2021 05:02:40'	System	26 Apr 2021 05:02:42

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-05-03T00:02:41-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8ffee477-3c07-4e58-a87d-5058db1fc694'	System	03 May 2021 05:02:49
User entered 'No (N)'	System	03 May 2021 05:02:49

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

Have you been exposed to someone with 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 (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-05-03T00:02:42-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8ffee477-3c07-4e58-a87d-5058db1fc694'	System	03 May 2021 05:02:49
User entered 'No (N)'	System	03 May 2021 05:02:49

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-05-03T00:02:44-05:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '8ffee477-3c07-4e58-a87d-5058db1fc694'	System	03 May 2021 05:02:49
User entered '03 May 2021 05:02:44'	System	03 May 2021 05:02:49

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:21:28

US3032323

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:28
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:21:28

US3032323

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:54:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:24:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-01T00:03:24-06:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '21a2c9b7-454a-4a7b-84b8-a7bc2caf2d3d'	System	01 Mar 2021 06:03:32
User entered 'No (N)'	System	01 Mar 2021 06:03:32

US3032323

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:54:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:24:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DE1E62C-810A-4DE0-B0CC-8D834C8E4679)', Time: '2021-03-01T00:03:27-06:00', User OID: 'PatientReportedOutcome (US3032323)', ODM File OID: '21a2c9b7-454a-4a7b-84b8-a7bc2caf2d3d' User entered '01 Mar 2021 06:03:27'	System	01 Mar 2021 06:03:32
	System	01 Mar 2021 06:03:32

US3032323

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:19
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Dec 2020 21:31:35

US3032323

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:19
User entered '16 Nov 2020'	(b) (4) Linden DeBoer (b) (4)	01 Dec 2020 21:31:35

US3032323

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4)	01 Dec 2020 21:31:35

US3032323

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:19
User entered empty.	(b) (4) Linden DeBoer (b) (4)	01 Dec 2020 21:31:35
	(b) (4)	

US3032323

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:19
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Dec 2020 21:31:52

US3032323

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:45:20
User entered 'I'	System	01 Dec 2020 21:31:52

US3032323

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Dec 2020 17:11:40

US3032323

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:54
User entered '18 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	21 Dec 2020 17:11:40

US3032323

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	21 Dec 2020 17:11:40

US3032323

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Dec 2020 17:11:40

US3032323

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Dec 2020 17:11:11

US3032323

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered 'I'	System	21 Dec 2020 17:11:11

US3032323

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:20

US3032323

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '19 Jan 2021'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:20

US3032323

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:20

US3032323

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:20
	(b) (4)	

US3032323

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:23

US3032323

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered '1'	System	24 Feb 2021 00:27:23

US3032323

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:41

US3032323

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '23 Feb 2021'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:41

US3032323

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:41

US3032323

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:27:41
	(b) (4)	

US3032323

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	24 Feb 2021 00:27:45

US3032323

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered '1'	System	24 Feb 2021 00:27:45

US3032323

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:07

US3032323

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered '1 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:07

US3032323

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:53:07

US3032323

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered 'VISIT4'	System	01 Apr 2021 19:53:07

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered empty.	System	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:46:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered empty.	System	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered empty.	System	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered empty.	System	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:17
	(b) (4)	

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered empty.	System	01 Apr 2021 19:53:17

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39

US3032323

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39

US3032323

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:23

US3032323

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 19:53:23

US3032323

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:33
	(b) (4)	

US3032323

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered '1 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:33
	(b) (4)	

US3032323

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered '14:23'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:33

US3032323

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered '1 Apr 2021 14:23'	System	01 Apr 2021 19:53:33

US3032323

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 19:53:35

US3032323

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:15:39
User entered '1'	System	01 Apr 2021 19:53:35

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 22:56:50

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:56:50

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 22:56:50

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered 'UNBLND_DECIDE'	System	02 Mar 2021 22:56:50

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:31
User entered '0'	(b) (4) Linden DeBoer (b) (4)	16 Mar 2021 16:45:34
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 13:40:26

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 22:57:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:31
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
Amendment Manager inserted this DataPoint.	Linden DeBoer (b) (4)	16 Mar 2021 16:45:34
	(b) (4)	
	System	06 Mar 2021 13:40:26

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:08
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:08
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:08
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 22:57:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered empty.	System	02 Mar 2021 22:57:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:54:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered empty.	System	02 Mar 2021 22:57:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:50

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:50

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '14:50'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:50

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered '23 Feb 2021 14:50'	System	02 Mar 2021 22:57:50

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:58

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:54:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '23 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 22:57:58

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:54:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '14:35'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 22:57:58

US3032323

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:54:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:12:26
User entered '23 Feb 2021 14:35'	System	02 Mar 2021 22:57:58

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:54:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:57:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:03
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 00:03:22
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	24 Feb 2021 00:03:22
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	15 Sep 2020 23:02:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'USA-US032-2021-mRNA-1273-P301000010'	(b) (4) System	24 Feb 2021 18:43:16
User entered 'New'	(b) (4), (b) (6)	24 Feb 2021 18:43:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGHT: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Spontaneous abortion - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:50:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:50:59
Data point term sent to Coder	System	24 Feb 2021 00:14:25
User entered 'Spontaneous Abortion of Pregnancy'	Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
System		24 Feb 2021 00:15:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 00:15:06
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	24 Feb 2021 00:15:06
(b) (4)		
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 00:13:35
User entered empty.	Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35
(b) (4)		

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	04 Mar 2021 16:05:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Mar 2021 20:40:16
User entered '02 Feb 2021' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	02 Mar 2021 20:40:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Feb 2021 16:54:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Feb 2021 16:54:03
User entered '00 Nov 2020' (non-conformant).	Linden DeBoer (b) (4) (b) (4)	27 Feb 2021 16:54:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Feb 2021 00:13:35
User entered 'UN Nov 2020' (non-conformant).	Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '02 Feb 2021'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	24 Feb 2021 00:15:06
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Feb 2021 00:13:35
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	04 Mar 2021 16:05:58
User entered '1' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:15:06
User entered '0'	Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:13:35

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 12:30:49
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'updated' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	02 Mar 2021 21:45:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	02 Mar 2021 21:45:16
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 21:38:30
User entered 'Not Applicable (NOT APPLICABLE)'	Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User closed query 'Per CDM CLR re-query: Per response however the indication is not SPONTANEOUS ABORTION OF PREGNANCY for Rhogam in Conmed, kindly review and amend as appropriate.' (Site from DM).		31 Mar 2021 12:21:40
Query 'Per CDM CLR re-query: Per response however the indication is not SPONTANEOUS ABORTION OF PREGNANCY for Rhogam in Conmed, kindly review and amend as appropriate.' answered with 'rhogam is not given due to spontaneous abortion. Rhogam was given due to her being RH positive when she had the spontaneous abortion. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	26 Mar 2021 13:42:11
User opened query 'Per CDM CLR re-query: Per response however the indication is not SPONTANEOUS ABORTION OF PREGNANCY for Rhogam in Conmed, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 02:57:26
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 02:57:26
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Rhogam is in ConMed' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 16:33:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:56:30
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '1'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	04 Mar 2021 16:05:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

US3032323

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User closed query 'PV Query: Please confirm if history of irregular menstrual cycles is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If history of irregular menstrual cycles is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 12:30:46
User closed query 'PV Query: Kindly query for any history of trauma or other risk prior to the event ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 12:30:34
User closed query 'PV Query: Were these abnormal symptoms such as bloating, nausea, and some upper respiratory symptoms reported as events? ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 12:30:11
Query 'PV Query: Were these abnormal symptoms such as bloating, nausea, and some upper respiratory symptoms reported as events? ' answered with 'bloating and nausea are symptoms of the pregnancy. we will go in and create an AE for the respiratory symptoms reported. ' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	02 Mar 2021 21:53:31
Query 'PV Query: Kindly query for any history of trauma or other risk prior to the event ' answered with 'no history of trauma' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	02 Mar 2021 21:44:09
Query 'PV Query: Please confirm if history of irregular menstrual cycles is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If history of irregular menstrual cycles is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' answered with 'updated medical history' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	02 Mar 2021 21:44:02
User opened query 'PV Query: Were these abnormal symptoms such as bloating, nausea, and some upper respiratory symptoms reported as events? ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 21:39:22
User opened query 'PV Query: Kindly query for any history of trauma or other risk prior to the event ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 21:38:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if history of irregular menstrual cycles is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If history of irregular menstrual cycles is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 21:38:13
User entered 'The subject reports she was experiencing abnormal symptoms such as bloating, nausea, and some upper respiratory symptoms. She saw her PCP who performed a covid test (negative) and pregnancy test (positive). The subject was unsure of the date she saw PCP. On 02Feb2021 the subject experienced heavy cramping and bleeding. She contacted an OBGYN who confirmed a spontaneous miscarriage had occurred. She is a negative blood type and was given a one time dose of Rhogam. The subject reports she had not received an ultrasound prior to the miscarriage. Records are pending and will update once received.'	Samantha Wieseler (b) (4)	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 00:13:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 00:13:35

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 23:01:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 23:01:48
Data point term sent to Coder	System	02 Mar 2021 23:01:04
User entered 'Upper respiratory infection'	Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '15 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
User entered empty.	System	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '23 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
User entered empty.	System	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.		31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '1'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
User entered '0'	System	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46
User entered '1'	System	02 Mar 2021 23:00:25

US3032323

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:54:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:47:46

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:54:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:57:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:44:20

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: DROSPIRENONE;ETHINYLESTRADIOL, PRODUCTSYNONYM: LORYNA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Sep 2020 05:43:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Sep 2020 05:43:43
Data point term sent to Coder	System	14 Sep 2020 23:02:19
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	14 Sep 2020 23:01:20
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'ConMed has been updated' (Site from System).	Samantha Wieseler (b) (4)	14 Sep 2020 23:01:20
Data point term sent to Coder	System	14 Sep 2020 23:01:18
User entered 'LORYNA	Samantha Wieseler (b) (4)	14 Sep 2020 23:01:08
"Drospirenone" reason for change: Data Entry Error	(b) (4)	(b) (4)
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	26 Aug 2020 12:00:39

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	22 Aug 2020 20:33:22
User entered 'loresta'	Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Birth control'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User closed query 'Per DM CLR: Please review if this is a combination medication; if yes; consider providing both component dose (Dose per administration= 3/0.0 2, Dose Unit = mg). Otherwise, kindly confirm data is correct as is.' (Site from DM).		20 Oct 2020 14:22:09
Query 'Per DM CLR: Please review if this is a combination medication; if yes; consider providing both component dose (Dose per administration= 3/0.0 2, Dose Unit = mg). Otherwise, kindly confirm data is correct as is.' answered with 'DATA IS CORRECT AS ENTERED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:55:11
User opened query 'Per DM CLR: Please review if this is a combination medication; if yes; consider providing both component dose (Dose per administration= 3/0.0 2, Dose Unit = mg). Otherwise, kindly confirm data is correct as is.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:15:03
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 23:01:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 23:01:08
User entered '3' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	14 Sep 2020 23:01:08
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 20:32:43
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Sep 2020 23:01:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 23:01:08
User entered 'mg (mg)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	14 Sep 2020 23:01:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Aug 2020 20:32:43
User entered empty.	System	22 Aug 2020 20:32:43
	Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:15:45
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 20:32:43
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 20:32:43

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: IMMUNE SERA AND IMMUNOGLOBULINS, ATC: IMMUNOGLOBULINS, ATC: SPECIFIC IMMUNOGLOBULINS, PRODUCT: ANTI-D IMMUNOGLOBULIN, PRODUCTSYNONYM: RHOGAM - version WHODrug-Global-B3\202003.	(b) (4) (b) (4) Coder Import (b) (4)	24 Feb 2021 00:19:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Feb 2021 00:19:16
Data point term sent to Coder	System	24 Feb 2021 00:18:30
Coding entries removed.	Samantha Wieseler (b) (4)	24 Feb 2021 00:18:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: IMMUNE SERA AND IMMUNOGLOBULINS, ATC: IMMUNOGLOBULINS, ATC: SPECIFIC IMMUNOGLOBULINS, PRODUCT: ANTI-D IMMUNOGLOBULIN, PRODUCTSYNONYM: RHOGAM - version WHODrug-Global-B3\202003.	(b) (4) (b) (4) Coder Import (b) (4)	24 Feb 2021 00:18:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Feb 2021 00:18:07
Data point term sent to Coder	System	24 Feb 2021 00:17:29
User entered 'Rhogam'	Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
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	24 Feb 2021 00:18:15
User entered 'Postpartum RH prophylaxis' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	24 Feb 2021 00:18:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	24 Feb 2021 00:17:22
	Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.	(b) (4)	31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '1'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Other (OTHER)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'ampule'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'once (ONCE)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '03 Feb 2021'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
DataPoint Verified.		31 Mar 2021 23:54:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '03 Feb 2021'	(b) (4) Samantha Wieseler (b) (4)	24 Feb 2021 00:17:22
	(b) (4)	

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:46:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 23:54:41
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).		25 Mar 2021 02:37:53
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 16:33:38
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 16:33:29
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 16:33:29
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:14:11
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	04 Mar 2021 16:05:58
User entered 'Yes (Y)'	Samantha Wieseler (b) (4) (b) (4)	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
User entered empty.	System	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
User entered empty.	System	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:36:04
User entered empty.	System	24 Feb 2021 00:17:22

US3032323

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:54:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:15:45
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 20:34:21
	(b) (4)	

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'USA-US032-2021-MRNA-1273-P301000010'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Yes (Y)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Yes (Y)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Keith'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Vrbicky'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:21:36
User entered 'US'	System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Mar 2021 16:29:35
User entered '2'	System	01 Mar 2021 15:21:52
User entered '1'	System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'USA-US032-2021-MRNA-1273-P301000010'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Yes (Y)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Yes (Y)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Keith'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Vrbicky'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:21:36
User entered 'US'	System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Mar 2021 16:29:35
User entered '2'	System	01 Mar 2021 15:21:52
User entered '1'	System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:54:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '24/Feb/2021 12:47'	(b) (4) System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:54:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:21:36
User entered '1'	(b) (4), (b) (6)	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'USA-US032-2021-MRNA-1273-P301000010'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Yes (Y)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Yes (Y)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Keith'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Vrbicky'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:21:36
User entered 'US'	System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Mar 2021 16:29:35
User entered '2'	System	01 Mar 2021 15:21:52
User entered '1'	System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:54:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '01/Mar/2021 10:21'	(b) (4) System	01 Mar 2021 15:21:52

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:54:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:14
User entered '1'	(b) (4), (b) (6)	01 Mar 2021 15:21:52

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'USA-US032-2021-MRNA-1273-P301000010'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Yes (Y)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'No (N)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Yes (Y)'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Keith'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:05
User entered 'Vrbicky'	System	24 Feb 2021 18:43:16

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:21:36
User entered 'US'	System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Mar 2021 16:29:35
User entered '2'	System	01 Mar 2021 15:21:52
User entered '1'	System	24 Feb 2021 18:47:15

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:54:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '01/Mar/2021 11:29'	(b) (4) System	01 Mar 2021 16:29:35

US3032323

Folder: SAE USA-US032-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:54:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:58
User entered '1'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:29:35