

US3242013 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:10:07

All time stamps listed in this document are displayed in GMT

US3242013

Form: Participant Creation

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Participant ID

US3242013

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

US3242013

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3242013

Folder: Screening

Form: Demographics

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Date of Birth (MMM yyyy)	(b) (6) 1987
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3242013

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Date of Informed Consent (*dd MMM yyyy*) 6 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

US3242013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Did the participant meet all eligibility criteria?

Yes

No

US3242013

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 06 AUG 2020

Time of assessment (00:00-23:59) 16:02 (24 HR)

Vital Signs Date and Time (derived) 06 AUG 2020 16:02

Height (xxx.x) 61.5 in

Weight (xxx.x) 151.3 lb

BMI (xxx.x) 28.18374 kg/m²

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) ND - Not Done

Pulse units BPM

Respiratory Rate (xxx) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 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) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

6 AUG 2020

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

US3242013

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 31 Aug 2020 13:46:02

Generated On: 09 Jun 2021 16:10:07

Date of assessment (*dd MMM yyyy*) 6 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) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 6 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) 31 Aug 2020 13:46:03

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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) 31 Aug 2020 13:46:03

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 6 AUG 2020

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

Folder OID VISIT1

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101672

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Height	ND - Not Done
Weight	ND - Not Done

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:02 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:02
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:56 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 17:56
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 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>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3242013

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

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.

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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) _____

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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) 06 AUG 2020

What was the treatment time? (00:00-23:59) 17:22 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 17:22

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

US3242013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 06 AUG 2020

Collection time (*00:00-23:59*) 16:59 (24 HR)

Collection date and time (derived) 06 AUG 2020 16:59

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Collection date (<i>dd MMM yyyy</i>)			06 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	16:44	06 AUG 2020 16:44
Nasopharyngeal Swab 2	No		

US3242013

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 13:46:02

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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 06 AUG 2020 17:56

PC Open Date & Time 06 AUG 2020 17:42

PC Close Date & Time 06 AUG 2020 20:12

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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 98.2 °F

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

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

PC Time Stamp 07 AUG 2020 10:58
PC Open Date & Time 06 AUG 2020 21:07
PC Close Date & Time 07 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

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	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 AUG 2020 10:07
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °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	09 AUG 2020 01:51
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

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	96.8 °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	09 AUG 2020 22:24
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °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	11 AUG 2020 07:15
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

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	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 AUG 2020 09:19
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

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	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 AUG 2020 21:10
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

06 AUG 2020 17:57

PC Open Date & Time

06 AUG 2020 17:42

PC Close Date & Time

06 AUG 2020 20:12

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

07 AUG 2020 11:01

PC Open Date & Time

06 AUG 2020 21:07

PC Close Date & Time

07 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

08 AUG 2020 10:07

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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	09 AUG 2020 01:52
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

09 AUG 2020 22:24

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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	11 AUG 2020 07:15
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

12 AUG 2020 09:19

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

12 AUG 2020 21:10

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

No

Yes

PC Time stamp	06 AUG 2020 17:57
PC Open Date & Time	06 AUG 2020 17:42
PC Close Date & Time	06 AUG 2020 20:12

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

No
Yes

PC Time stamp	07 AUG 2020 11:02
PC Open Date & Time	06 AUG 2020 21:07
PC Close Date & Time	07 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 10:08
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 01:52
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 22:25
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

Yes

PC Time stamp	11 AUG 2020 07:16
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

Yes

PC Time stamp	12 AUG 2020 09:20
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 21:10
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3242013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 13:46:02

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 13:46:02

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 3 SEP 2020

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

Folder OID VISIT2

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:37 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 15:37
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	17:07 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 17:07
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	62 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>)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3242013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 03 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 16:37 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 16:37

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

US3242013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	03 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:22 (24 HR)
Collection date and time (derived)	03 SEP 2020 16:22

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Collection date (<i>dd MMM yyyy</i>)			03 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	16:15	03 SEP 2020 16:15
Nasopharyngeal Swab 2	No		

US3242013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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 03 SEP 2020 17:09

PC Open Date & Time 03 SEP 2020 16:57

PC Close Date & Time 03 SEP 2020 19:27

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp 04 SEP 2020 08:13
PC Open Date & Time 03 SEP 2020 20:22
PC Close Date & Time 04 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

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

PC Time Stamp	05 SEP 2020 00:54
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °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	06 SEP 2020 06:03
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

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

PC Time Stamp	07 SEP 2020 08:17
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 05:51
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

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	97.7 °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	08 SEP 2020 21:16
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp 10 SEP 2020 08:36

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

03 SEP 2020 17:09

PC Open Date & Time

03 SEP 2020 16:57

PC Close Date & Time

03 SEP 2020 19:27

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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	04 SEP 2020 08:13
PC Open Date & Time	03 SEP 2020 20:22
PC Close Date & Time	04 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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	05 SEP 2020 00:55
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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	06 SEP 2020 06:03
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

07 SEP 2020 08:18

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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	08 SEP 2020 05:52
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

08 SEP 2020 21:17

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

10 SEP 2020 08:37

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

No

Yes

PC Time stamp	03 SEP 2020 17:10
PC Open Date & Time	03 SEP 2020 16:57
PC Close Date & Time	03 SEP 2020 19:27

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

No

Yes

PC Time stamp	04 SEP 2020 08:13
PC Open Date & Time	03 SEP 2020 20:22
PC Close Date & Time	04 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 00:55
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 06:04
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 08:18
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 05:52
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 21:17
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 08:37
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3242013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 01 OCT 2020

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

Folder OID VISIT3

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 18:04:44

Generated On: 09 Jun 2021 16:10:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:15 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 15:15
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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.

US3242013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 01 OCT 2020

Collection time (*00:00-23:59*) 15:31 (24 HR)

Collection date and time (derived) 01 OCT 2020 15:31

US3242013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 06 OCT 2020 18:52:54

Patient Cloud Open Date & Time 06 OCT 2020 00:01

Patient Cloud Close Date & Time 10 OCT 2020 23:59

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 14 OCT 2020 07:51:24

Patient Cloud Open Date & Time 13 OCT 2020 00:01

Patient Cloud Close Date & Time 17 OCT 2020 23:59

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 21 OCT 2020 17:52:03

Patient Cloud Open Date & Time 20 OCT 2020 00:01

Patient Cloud Close Date & Time 24 OCT 2020 23:59

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 05 NOV 2020 09:36:04

Patient Cloud Open Date & Time 03 NOV 2020 00:01

Patient Cloud Close Date & Time 07 NOV 2020 23:59

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 99

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

No

Yes

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

No

Yes

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

Date and time of submission 10 NOV 2020 15:34:52

Patient Cloud Open Date & Time 10 NOV 2020 00:01

Patient Cloud Close Date & Time 14 NOV 2020 23:59

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 106

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

No

Yes

Have you been exposed to someone with known SARS-CoV-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 17 NOV 2020 11:34:18

Patient Cloud Open Date & Time 17 NOV 2020 00:01

Patient Cloud Close Date & Time 21 NOV 2020 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 14:41:59
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 30 NOV 2020 09:05:53

Patient Cloud Open Date & Time 28 NOV 2020 00:01

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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	05 DEC 2020 00:07:12
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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	12 DEC 2020 10:43:06
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 138

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

No

Yes

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

No

Yes

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

Date and time of submission 19 DEC 2020 07:20:16

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 28 DEC 2020 08:31:41

Patient Cloud Open Date & Time 26 DEC 2020 00:01

Patient Cloud Close Date & Time 30 DEC 2020 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 <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 13:59:15
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 159

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

No
Yes

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

No
Yes

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

Date and time of submission	11 JAN 2021 16:49:45
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 <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	18 JAN 2021 10:25:06
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 <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	23 JAN 2021 08:39:37
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 14:10:28
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 <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	06 FEB 2021 09:36:49
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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	13 FEB 2021 11:16:48
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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	20 FEB 2021 00:15:29
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 11:12:54
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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	06 MAR 2021 07:32:57
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission 14 MAR 2021 22:08:50

Patient Cloud Open Date & Time 13 MAR 2021 00:01

Patient Cloud Close Date & Time 17 MAR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 10:57:55
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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	30 MAR 2021 14:01:48
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 05 APR 2021 11:50:50

Patient Cloud Open Date & Time 03 APR 2021 00:01

Patient Cloud Close Date & Time 07 APR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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	12 APR 2021 16:55:03
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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	17 APR 2021 10:04:00
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 264

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

No

Yes

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

No

Yes

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

Date and time of submission 27 APR 2021 08:25:16

Patient Cloud Open Date & Time 24 APR 2021 00:01

Patient Cloud Close Date & Time 28 APR 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	22 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	29 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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°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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#) 30 JUN 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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°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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 OCT 2021 00:01

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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°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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 08 DEC 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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°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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	08 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#) 09 MAR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 APR 2022 00:01

[Patient Cloud Close Date & Time](#) 06 APR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2022 00:01
Patient Cloud Close Date & Time	25 MAY 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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°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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 10 AUG 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 740

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

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

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

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

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

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

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3242013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:10:07

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		27 FEB 2021 11:13:07

US3242013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 MAR 2021

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

Folder OID VISIT4

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:38:21

Generated On: 09 Jun 2021 16:10:07

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) _____

US3242013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

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.

US3242013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 11 MAR 2021

Collection time (*00:00-23:59*) 15:50 (24 HR)

Collection date and time (derived) 11 MAR 2021 15:50

US3242013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 19:38:21

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 30 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:38:21

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 13:49:42

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

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 _____

US3242013

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3242013

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Date of Contact _____

Time of Contact _____

Date and Time of Contact (derived) _____

Type of Contact

Clinic Visit - Scheduled

Clinical Visit - Unscheduled

Safety Call

Convalescent Tele-visit

Has the subject reported symptoms of SARS-COV-2? Yes

No

US3242013

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Generate Next COVID-19 Assessment

Yes

No

US3242013

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

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 JAN 2021

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

Folder OID UNBLND_DECIDE

US3242013

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Date of updated informed consent (<i>dd MMM yyyy</i>)	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3242013

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3242013

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	15:56 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 15:56
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3242013

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	17:07 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 17:07
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3242013

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

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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.

US3242013

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

Form: Pregnancy Test

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 26 JAN 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3242013

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

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 16:35 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 16:35

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

US3242013

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 JAN 2021

Collection time (*00:00-23:59*) 15:39 (24 HR)

Collection date and time (derived) 26 JAN 2021 15:39

US3242013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Feb 2021 18:04:14

Generated On: 09 Jun 2021 16:10:07

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 JAN 2021

Collection time (*00:00 - 23:59*) 15:32

Collection Date and Time (derived) 26 JAN 2021 15:32

US3242013

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

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:14

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:04:43

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 MAR 2021

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

Folder OID OLD29

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Timepoint Pre-Dose
Post-Dose

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 _____

US3242013

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

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.

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 20 Apr 2021 21:17:30

Generated On: 09 Jun 2021 16:10:07

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 11 MAR 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3242013

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3242013

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:09:14

Generated On: 09 Jun 2021 16:10:07

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3242013

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:09:14

Generated On: 09 Jun 2021 16:10:07

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3242013

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Apr 2021 21:17:31

Generated On: 09 Jun 2021 16:10:07

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID OLD57

US3242013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3242013

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

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.

US3242013

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 20 Apr 2021 21:17:31

Generated On: 09 Jun 2021 16:10:07

Visit Date	19 APR 2021
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	False
---------------	-------

Vital Signs	True
-------------	------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	True
----------------	------

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Data signed: (b) (4) **20 Apr 2021 21:17:31**

Generated On: **09 Jun 2021 16:10:07**

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 APR 2021
Time of assessment (<i>00:00-23:59</i>)	16:14 (24 HR)
Vital Signs Date and Time (derived)	19 APR 2021 16:14
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Data signed: (b) (4) 20 Apr 2021 21:17:31

Generated On: 09 Jun 2021 16:10:07

Was the pregnancy test performed? Yes
No

Date of test (*dd MMM yyyy*) 19 APR 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3242013

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 20:52:59

Generated On: 09 Jun 2021 16:10:07

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

AEID USA-US067-2021-MRNA-1273-P30
1000013

Adverse event SPONTANEOUS ABORTION

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) 17 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 17 MAR 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 True

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

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

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 <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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	SUBJECT EXPERIENCED A MISCARRIAGE ON 3/17/2021. SUBJECT WENT TO ER DUE TO EXTREMELY HEAVY BLEEDING AND WAS INFORMED OF A MISCARRIAGE. NO OTHER PROBLEMS AND DOING WELL.

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Mar 2021 15:55:05

Generated On: 09 Jun 2021 16:10:07

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

Yes

No

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

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

Name of Medication PRENATAL MULTIVITAMIN

Prophylaxis Yes
No

Indication SUPPLEMENT FOR PREGNANCY

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 1936

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

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*) 22 FEB 2021

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

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

Name of Medication KETOROLAC

Prophylaxis Yes
No

Indication SPONTANEOUS ABORTION

Dose per administration 30

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 1936

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

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 checked="" 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*) 17 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 17 MAR 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

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

Name of Medication MISOPROSTOL

Prophylaxis Yes
No

Indication SPONTANEOUS ABORTION

Dose per administration TAPERING DOSE

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 1936

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

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*) 17 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 17 MAR 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

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes
No

Indication SPONTANEOUS ABORTION

Dose per administration 0.9

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify %

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 1936

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:10:07

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 checked="" 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*) 17 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 17 MAR 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

US3242013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3242013

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Due to SARS-COV-2

Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3242013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 31 Aug 2020 13:46:03

Generated On: 09 Jun 2021 16:10:07

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

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 14:11:31

Generated On: 09 Jun 2021 16:10:07

SAEID	USA-US067-2021-MRNA-1273-P30 1000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 14:11:31

Generated On: 09 Jun 2021 16:10:07

SAEID	USA-US067-2021-MRNA-1273-P30 1000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/APR/2021 13:08
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

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 14:11:31

Generated On: 09 Jun 2021 16:10:07

SAEID	USA-US067-2021-MRNA-1273-P30 1000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/APR/2021 09:39
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

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 14:11:31

Generated On: 09 Jun 2021 16:10:07

SAEID	USA-US067-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/APR/2021 15:47
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.	<input checked="" type="checkbox"/> True

Audit

US3242013 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242013

Form: Participant Creation

Generated On: 09 Jun 2021 16:10:07

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:31:44
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'US3242013'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 19:49:27

US3242013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:32:40
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:04:37

US3242013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:32:40
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 19:49:28

US3242013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:32:40
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	06 Aug 2020 21:04:37

US3242013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'SCRN'	(b) (4), (b) (6) System	06 Aug 2020 21:04:37

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered (b) (6) 1987'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 19:49:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '33'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'YEARS'	(b) (4), (b) (6) System	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '33'	(b) (4), (b) (6) System	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Female (F)'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '1'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:07

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:33:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:29

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:34:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'Aug 2020'	(b) (4), (b) (6) System	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '2020'	(b) (4), (b) (6) System	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:34:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Amendment 1 (1)'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:34:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:34:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:34:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:34:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:42

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:34:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 19:49:28

US3242013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '1'	(b) (4), (b) (6) System	06 Aug 2020 21:05:45

US3242013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:35:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:45

US3242013

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:10:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:36:33
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:05:56

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:26:07
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:26:07
User entered '06 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:26:07
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '16:02'	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
User entered '06 Aug 2020 16:02'	(b) (4), (b) (6)	
	System	19 Nov 2020 20:26:07
User entered '6 Aug 2020 16:02'	System	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '61.5' in	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52
DataPoint set to visible.	System	06 Aug 2020 21:05:45

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '151.3' lb	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52
DataPoint set to visible.	System	06 Aug 2020 21:05:45

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
Amendment Manager: User entered '28.18374'	(b) (4), (b) (6)	
User entered '28.2'	System	16 Sep 2020 23:46:19
DataPoint set to visible.	System	06 Aug 2020 21:06:52
	System	06 Aug 2020 21:05:45

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
User entered 'kg/m2'	(b) (4), (b) (6)	06 Aug 2020 21:06:52
DataPoint set to visible.	System	06 Aug 2020 21:05:45

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:17:03
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:45:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:45:46
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:46:08
User entered '97.9' F	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:45:46
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:45:46
User entered '60'	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
User entered 'bpm'	(b) (4), (b) (6) System	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:45:46
User entered '18'	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
User entered 'breaths/min'	(b) (4), (b) (6) System	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:45:46
User entered '90'	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:45:46
User entered '70'	Donna Toepfer (b) (4)	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 21:06:52

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
	(b) (4), (b) (6)	

US3242013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:36
	(b) (4), (b) (6)	

US3242013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:08:55

US3242013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:40:25
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:36:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 20:27:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:08:55

US3242013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:41:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:10:29

US3242013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:41:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:10:29

US3242013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:41:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:10:29

US3242013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:07

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:41:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:10:29

US3242013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:41:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:10:29

US3242013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:07

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:41:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:10:29

US3242013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:41:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:10:29

US3242013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:07

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:41:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:10:29

US3242013

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:42:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:12:34

US3242013

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:42:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:12:34

US3242013

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:42:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Urine (URINE)'	Donna Toepfer (b) (4)	06 Aug 2020 21:12:34

US3242013

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:42:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Negative (NEGATIVE)'	Donna Toepfer (b) (4)	06 Aug 2020 21:12:34

US3242013

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:42:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:12:34

US3242013

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:42:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:12:34

US3242013

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:42:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:12:34

US3242013

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 21:12:34

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '1'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '0'	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 14:04:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:11:48

US3242013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:12:48

US3242013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:12:48

US3242013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[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 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	06 Aug 2020 21:12:48

US3242013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'VISIT1'	System	06 Aug 2020 21:12:48

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 21:04:23

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:07

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:40:44
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:40:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 21:04:23
User entered '101672' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 21:04:23

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 21:04:23

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:07

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 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:13:05

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:07

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 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:13:05

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:13:05

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:13:05

US3242013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:13:05

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:46:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:46:07
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:46:21
User entered '61.5' in	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:46:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:46:07
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:46:26
User entered '151.3' lb	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:46:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:46:07
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:46:21
User entered '61.5' in	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:46:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:46:07
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:46:26
User entered '151.3' lb	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:29:39
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:29:39
User entered '06 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:29:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '16:02'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered '06 Aug 2020 16:02'	System	19 Nov 2020 20:29:39
User entered '6 Aug 2020 16:02'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '97.9' F	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '60'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'bpm'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '18'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'breaths/min'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '90'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '70'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:46:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:46:07
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:46:21
User entered '61.5' in	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:46:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:46:07
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:46:26
User entered '151.3' lb	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:29:39
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:29:39
User entered '06 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:29:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 07:33:32
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 mins per protocol' (Site from System).	Donna Toepfer (b) (4)	06 Aug 2020 23:09:48
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		06 Aug 2020 23:09:26
User entered '17:56'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User entered '06 Aug 2020 17:56'	System	19 Nov 2020 20:29:39
User entered '6 Aug 2020 17:56'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '97.7' F	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '64'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'bpm'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '15'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'breaths/min'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '107'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:25
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '82'	Donna Toepfer (b) (4)	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	System	06 Aug 2020 23:09:26

US3242013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:13:13

US3242013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:38
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:13:13

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:13:17

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:13:17

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:13:17

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:13:17

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:53
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	24 Sep 2020 13:00:35
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	24 Sep 2020 13:00:35
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:13:17

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:13:17

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:46:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:13:17

US3242013

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 21:13:17

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:47:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:47:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

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 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:47:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:14
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:14
User entered '06 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:47:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:47:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '17:22'	Donna Toepfer (b) (4)	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User entered '06 Aug 2020 17:22'	System	19 Nov 2020 20:30:14
User entered '6 Aug 2020 17:22'	System	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:47:18
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:47:18
User entered 'ONCE'	System	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 21:29:37

US3242013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:47:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:14:41

US3242013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:26
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:26
User entered '06 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:47:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:14:41

US3242013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:47:39
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '16:59'	Donna Toepfer (b) (4)	06 Aug 2020 21:14:41

US3242013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User entered '06 Aug 2020 16:59'	System	19 Nov 2020 20:30:26
User entered '6 Aug 2020 16:59'	System	06 Aug 2020 21:14:41

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:10:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:40
Signature has been broken.	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:40
User entered '06 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	19 Nov 2020 20:30:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:48:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '6 Aug 2020'	Donna Toepfer (b) (4)	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:48:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:48:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '16:44'	Donna Toepfer (b) (4)	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User entered '06 Aug 2020 16:44'	System	19 Nov 2020 20:30:40
User entered '6 Aug 2020 16:44'	System	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:48:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:48:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 21:15:03

US3242013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:48:31
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Aug 2020 21:15:10

US3242013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered '1'	(b) (4), (b) (6) System	06 Aug 2020 21:15:10

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	System	06 Aug 2020 21:29:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:55:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '55364032-d8cb-4987-807b-6ed8a34a352e'	System	06 Aug 2020 21:56:27
User entered 'Yes (Y)'	System	06 Aug 2020 21:56:27

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:56:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '55364032-d8cb-4987-807b-6ed8a34a352e' User entered '97.7'	(b) (4), (b) (6) System	06 Aug 2020 21:56:27
	System	06 Aug 2020 21:56:27

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:56:06', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '55364032-d8cb-4987-807b-6ed8a34a352e'	(b) (4), (b) (6) System	06 Aug 2020 21:56:27
User entered 'No (N)'	System	06 Aug 2020 21:56:27

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:56:24', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '55364032-d8cb-4987-807b-6ed8a34a352e'	(b) (4), (b) (6) System	06 Aug 2020 21:56:27
User entered '06 Aug 2020 17:56'	System	06 Aug 2020 21:56:27

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 17:42'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 20:12'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6) System	06 Aug 2020 21:29:37
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T10:58:20', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'bc3b8690-e19b-4ccc-a9bf-437c20356b49'	(b) (4), (b) (6) System	07 Aug 2020 14:58:57
User entered 'Yes (Y)'	System	07 Aug 2020 14:58:57

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T10:58:42', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'bc3b8690-e19b-4ccc-a9bf-437c20356b49'	(b) (4), (b) (6) System	07 Aug 2020 14:58:57
User entered '98.2'	System	07 Aug 2020 14:58:57

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T10:58:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'bc3b8690-e19b-4ccc-a9bf-437c20356b49'	(b) (4), (b) (6) System	07 Aug 2020 14:58:57
User entered 'No (N)'	System	07 Aug 2020 14:58:57

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T10:58:51', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'bc3b8690-e19b-4ccc-a9bf-437c20356b49'	(b) (4), (b) (6) System	07 Aug 2020 14:58:57
User entered '07 Aug 2020 10:58'	System	07 Aug 2020 14:58:57

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 21:07'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:06:37', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a615729c-0a56-4391-92d6-bbbd9c1670a1'	(b) (4), (b) (6) System	08 Aug 2020 14:07:06
User entered 'Yes (Y)'	System	08 Aug 2020 14:07:06

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:06:52', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a615729c-0a56-4391-92d6-bbbd9c1670a1'	(b) (4), (b) (6) System	08 Aug 2020 14:07:06
User entered '97.3'	System	08 Aug 2020 14:07:06

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:06:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a615729c-0a56-4391-92d6-bbbd9c1670a1'	(b) (4), (b) (6) System	08 Aug 2020 14:07:06
User entered 'No (N)'	System	08 Aug 2020 14:07:06

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a615729c-0a56-4391-92d6-bbbd9c1670a1'	(b) (4), (b) (6) System	08 Aug 2020 14:07:06
User entered '08 Aug 2020 10:07'	System	08 Aug 2020 14:07:06

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:51:31', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '4427dbca-94ec-4249-91f4-4e876ce77d86'	(b) (4), (b) (6) System	09 Aug 2020 05:51:53
User entered 'Yes (Y)'	System	09 Aug 2020 05:51:53

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:51:42', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '4427dbca-94ec-4249-91f4-4e876ce77d86'	(b) (4), (b) (6) System	09 Aug 2020 05:51:53
User entered '98.7'	System	09 Aug 2020 05:51:53

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:51:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '4427dbca-94ec-4249-91f4-4e876ce77d86'	(b) (4), (b) (6) System	09 Aug 2020 05:51:53
User entered 'No (N)'	System	09 Aug 2020 05:51:53

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:51:51', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '4427dbca-94ec-4249-91f4-4e876ce77d86'	(b) (4), (b) (6) System	09 Aug 2020 05:51:53
User entered '09 Aug 2020 01:51'	System	09 Aug 2020 05:51:53

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:13', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5eae6606-e406-44fe-a36a-20821279d07c'	(b) (4), (b) (6) System	10 Aug 2020 02:24:36
User entered 'Yes (Y)'	System	10 Aug 2020 02:24:36

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:26', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5eae6606-e406-44fe-a36a-20821279d07c'	(b) (4), (b) (6) System	10 Aug 2020 02:24:36
User entered '96.8'	System	10 Aug 2020 02:24:36

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:31', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5eae6606-e406-44fe-a36a-20821279d07c'	(b) (4), (b) (6) System	10 Aug 2020 02:24:36
User entered 'No (N)'	System	10 Aug 2020 02:24:36

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:34', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5eae6606-e406-44fe-a36a-20821279d07c'	(b) (4), (b) (6) System	10 Aug 2020 02:24:36
User entered '09 Aug 2020 22:24'	System	10 Aug 2020 02:24:36

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 5'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:14', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'fb355577-73fa-4966-b2a7-87779c027d58'	(b) (4), (b) (6) System	11 Aug 2020 11:15:36
User entered 'Yes (Y)'	System	11 Aug 2020 11:15:36

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:25', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'fb355577-73fa-4966-b2a7-87779c027d58'	(b) (4), (b) (6) System	11 Aug 2020 11:15:36
User entered '98.7'	System	11 Aug 2020 11:15:36

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:28', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'fb355577-73fa-4966-b2a7-87779c027d58'	(b) (4), (b) (6) System	11 Aug 2020 11:15:36
User entered 'No (N)'	System	11 Aug 2020 11:15:36

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:35', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'fb355577-73fa-4966-b2a7-87779c027d58'	(b) (4), (b) (6) System	11 Aug 2020 11:15:36
User entered '11 Aug 2020 07:15'	System	11 Aug 2020 11:15:36

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 6'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:18:44', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a326174f-7b43-479e-895f-297d280835ee'	(b) (4), (b) (6) System	12 Aug 2020 14:04:56
User entered 'Yes (Y)'	System	12 Aug 2020 14:04:56

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:18:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a326174f-7b43-479e-895f-297d280835ee'	(b) (4), (b) (6) System	12 Aug 2020 14:04:56
User entered '98.1'	System	12 Aug 2020 14:04:56

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:18:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a326174f-7b43-479e-895f-297d280835ee'	(b) (4), (b) (6) System	12 Aug 2020 14:04:56
User entered 'No (N)'	System	12 Aug 2020 14:04:56

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:08', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a326174f-7b43-479e-895f-297d280835ee'	(b) (4), (b) (6) System	12 Aug 2020 14:04:56
User entered '12 Aug 2020 09:19'	System	12 Aug 2020 14:04:56

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 7'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:03', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1ad16f1b-b6c3-47d8-8f5d-9b8636285d1f'	(b) (4), (b) (6) System	13 Aug 2020 01:10:19
User entered 'Yes (Y)'	System	13 Aug 2020 01:10:19

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:11', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1ad16f1b-b6c3-47d8-8f5d-9b8636285d1f' User entered '98.1'	(b) (4), (b) (6) System	13 Aug 2020 01:10:19
	System	13 Aug 2020 01:10:19

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:15', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1ad16f1b-b6c3-47d8-8f5d-9b8636285d1f'	(b) (4), (b) (6) System	13 Aug 2020 01:10:19
User entered 'No (N)'	System	13 Aug 2020 01:10:19

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:17', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1ad16f1b-b6c3-47d8-8f5d-9b8636285d1f'	(b) (4), (b) (6) System	13 Aug 2020 01:10:19
User entered '12 Aug 2020 21:10'	System	13 Aug 2020 01:10:19

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:56:42', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'cec7a595-d805-4297-8618-08e40a99dfff'	(b) (4), (b) (6) System	06 Aug 2020 21:57:11
User entered 'None (1)'	System	06 Aug 2020 21:57:11

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:56:53', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'cec7a595-d805-4297-8618-08e40a99dfff'	(b) (4), (b) (6) System	06 Aug 2020 21:57:11
User entered 'No (N)'	System	06 Aug 2020 21:57:11

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:56:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'cec7a595-d805-4297-8618-08e40a99dfff'	(b) (4), (b) (6) System	06 Aug 2020 21:57:11
User entered 'No (N)'	System	06 Aug 2020 21:57:11

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'cec7a595-d805-4297-8618-08e40a99dfff'	(b) (4), (b) (6) System	06 Aug 2020 21:57:11
User entered 'None (1)'	System	06 Aug 2020 21:57:11

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:07', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'cec7a595-d805-4297-8618-08e40a99dfff'	(b) (4), (b) (6) System	06 Aug 2020 21:57:11
User entered '06 Aug 2020 17:57'	System	06 Aug 2020 21:57:11

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 17:42'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 20:12'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6) System	06 Aug 2020 21:29:37
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:00:42', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1020d5ed-5a69-41dc-8f05-25ac3705761f'	(b) (4), (b) (6) System	07 Aug 2020 15:01:08
User entered 'None (1)'	System	07 Aug 2020 15:01:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:00:46', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1020d5ed-5a69-41dc-8f05-25ac3705761f'	(b) (4), (b) (6) System	07 Aug 2020 15:01:08
User entered 'No (N)'	System	07 Aug 2020 15:01:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:00:55', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1020d5ed-5a69-41dc-8f05-25ac3705761f'	(b) (4), (b) (6) System	07 Aug 2020 15:01:08
User entered 'No (N)'	System	07 Aug 2020 15:01:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:01:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1020d5ed-5a69-41dc-8f05-25ac3705761f'	(b) (4), (b) (6) System	07 Aug 2020 15:01:08
User entered 'None (1)'	System	07 Aug 2020 15:01:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:01:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1020d5ed-5a69-41dc-8f05-25ac3705761f'	(b) (4), (b) (6) System	07 Aug 2020 15:01:08
User entered '07 Aug 2020 11:01'	System	07 Aug 2020 15:01:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 21:07'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:07', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '2389772f-d388-48cc-b328-a545a42605f3'	(b) (4), (b) (6) System	08 Aug 2020 14:07:47
User entered 'None (1)'	System	08 Aug 2020 14:07:47

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:11', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '2389772f-d388-48cc-b328-a545a42605f3'	(b) (4), (b) (6) System	08 Aug 2020 14:07:47
User entered 'No (N)'	System	08 Aug 2020 14:07:47

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:27', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '2389772f-d388-48cc-b328-a545a42605f3'	(b) (4), (b) (6) System	08 Aug 2020 14:07:47
User entered 'No (N)'	System	08 Aug 2020 14:07:47

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:40', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '2389772f-d388-48cc-b328-a545a42605f3'	(b) (4), (b) (6) System	08 Aug 2020 14:07:47
User entered 'None (1)'	System	08 Aug 2020 14:07:47

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:43', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '2389772f-d388-48cc-b328-a545a42605f3'	(b) (4), (b) (6) System	08 Aug 2020 14:07:47
User entered '08 Aug 2020 10:07'	System	08 Aug 2020 14:07:47

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:51:55', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f2775593-6e1b-4e31-927d-26c3a2faeec4'	(b) (4), (b) (6) System	09 Aug 2020 05:52:08
User entered 'None (1)'	System	09 Aug 2020 05:52:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:51:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f2775593-6e1b-4e31-927d-26c3a2faeec4'	(b) (4), (b) (6) System	09 Aug 2020 05:52:08
User entered 'No (N)'	System	09 Aug 2020 05:52:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f2775593-6e1b-4e31-927d-26c3a2faeec4'	(b) (4), (b) (6) System	09 Aug 2020 05:52:08
User entered 'No (N)'	System	09 Aug 2020 05:52:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f2775593-6e1b-4e31-927d-26c3a2faeec4'	(b) (4), (b) (6) System	09 Aug 2020 05:52:08
User entered 'None (1)'	System	09 Aug 2020 05:52:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:07', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f2775593-6e1b-4e31-927d-26c3a2faeec4'	(b) (4), (b) (6) System	09 Aug 2020 05:52:08
User entered '09 Aug 2020 01:52'	System	09 Aug 2020 05:52:08

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:37', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'df7545e8-65f1-4834-96f0-7b3f610c8c53'	(b) (4), (b) (6) System	10 Aug 2020 02:24:53
User entered 'None (1)'	System	10 Aug 2020 02:24:53

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:40', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'df7545e8-65f1-4834-96f0-7b3f610c8c53'	(b) (4), (b) (6) System	10 Aug 2020 02:24:53
User entered 'No (N)'	System	10 Aug 2020 02:24:53

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:44', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'df7545e8-65f1-4834-96f0-7b3f610c8c53'	(b) (4), (b) (6) System	10 Aug 2020 02:24:53
User entered 'No (N)'	System	10 Aug 2020 02:24:53

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'df7545e8-65f1-4834-96f0-7b3f610c8c53'	(b) (4), (b) (6) System	10 Aug 2020 02:24:53
User entered 'None (1)'	System	10 Aug 2020 02:24:53

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:51', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'df7545e8-65f1-4834-96f0-7b3f610c8c53'	(b) (4), (b) (6) System	10 Aug 2020 02:24:53
User entered '09 Aug 2020 22:24'	System	10 Aug 2020 02:24:53

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 5'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:39', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8baceb26-6c48-49bb-bd11-9f40663911c1'	(b) (4), (b) (6) System	11 Aug 2020 11:15:54
User entered 'None (1)'	System	11 Aug 2020 11:15:54

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:42', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8baceb26-6c48-49bb-bd11-9f40663911c1'	(b) (4), (b) (6) System	11 Aug 2020 11:15:54
User entered 'No (N)'	System	11 Aug 2020 11:15:54

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:45', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8baceb26-6c48-49bb-bd11-9f40663911c1'	(b) (4), (b) (6) System	11 Aug 2020 11:15:54
User entered 'No (N)'	System	11 Aug 2020 11:15:54

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8baceb26-6c48-49bb-bd11-9f40663911c1'	(b) (4), (b) (6) System	11 Aug 2020 11:15:54
User entered 'None (1)'	System	11 Aug 2020 11:15:54

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:53', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8baceb26-6c48-49bb-bd11-9f40663911c1'	(b) (4), (b) (6) System	11 Aug 2020 11:15:54
User entered '11 Aug 2020 07:15'	System	11 Aug 2020 11:15:54

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 6'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:19', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5ef82ca5-116c-477e-a6d8-83297d8db8f2'	(b) (4), (b) (6) System	12 Aug 2020 14:05:02
User entered 'None (1)'	System	12 Aug 2020 14:05:02

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:28', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5ef82ca5-116c-477e-a6d8-83297d8db8f2'	(b) (4), (b) (6) System	12 Aug 2020 14:05:02
User entered 'No (N)'	System	12 Aug 2020 14:05:02

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:31', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5ef82ca5-116c-477e-a6d8-83297d8db8f2'	(b) (4), (b) (6) System	12 Aug 2020 14:05:02
User entered 'No (N)'	System	12 Aug 2020 14:05:02

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:34', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5ef82ca5-116c-477e-a6d8-83297d8db8f2'	(b) (4), (b) (6) System	12 Aug 2020 14:05:02
User entered 'None (1)'	System	12 Aug 2020 14:05:02

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:39', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5ef82ca5-116c-477e-a6d8-83297d8db8f2'	(b) (4), (b) (6) System	12 Aug 2020 14:05:02
User entered '12 Aug 2020 09:19'	System	12 Aug 2020 14:05:02

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 7'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '52b267ca-013e-498b-9f2c-8abb56e34917'	(b) (4), (b) (6) System	13 Aug 2020 01:10:36
User entered 'None (1)'	System	13 Aug 2020 01:10:36

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:24', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '52b267ca-013e-498b-9f2c-8abb56e34917'	(b) (4), (b) (6) System	13 Aug 2020 01:10:36
User entered 'No (N)'	System	13 Aug 2020 01:10:36

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:26', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '52b267ca-013e-498b-9f2c-8abb56e34917'	(b) (4), (b) (6) System	13 Aug 2020 01:10:36
User entered 'No (N)'	System	13 Aug 2020 01:10:36

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:28', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '52b267ca-013e-498b-9f2c-8abb56e34917'	(b) (4), (b) (6) System	13 Aug 2020 01:10:36
User entered 'None (1)'	System	13 Aug 2020 01:10:36

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:31', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '52b267ca-013e-498b-9f2c-8abb56e34917'	(b) (4), (b) (6) System	13 Aug 2020 01:10:36
User entered '12 Aug 2020 21:10'	System	13 Aug 2020 01:10:36

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:14', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'daf67b49-6ab3-4334-ad23-f57d6f9c5ca3'	(b) (4), (b) (6) System	06 Aug 2020 21:57:38
User entered 'None (0)'	System	06 Aug 2020 21:57:38

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:17', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'daf67b49-6ab3-4334-ad23-f57d6f9c5ca3'	(b) (4), (b) (6) System	06 Aug 2020 21:57:38
User entered 'None (0)'	System	06 Aug 2020 21:57:38

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:19', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'daf67b49-6ab3-4334-ad23-f57d6f9c5ca3'	(b) (4), (b) (6) System	06 Aug 2020 21:57:38
User entered 'None (0)'	System	06 Aug 2020 21:57:38

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'daf67b49-6ab3-4334-ad23-f57d6f9c5ca3'	(b) (4), (b) (6) System	06 Aug 2020 21:57:38
User entered 'None (0)'	System	06 Aug 2020 21:57:38

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:22', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'daf67b49-6ab3-4334-ad23-f57d6f9c5ca3'	(b) (4), (b) (6) System	06 Aug 2020 21:57:38
User entered 'None (0)'	System	06 Aug 2020 21:57:38

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:25', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'daf67b49-6ab3-4334-ad23-f57d6f9c5ca3'	(b) (4), (b) (6) System	06 Aug 2020 21:57:38
User entered 'None (0)'	System	06 Aug 2020 21:57:38

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:28', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'daf67b49-6ab3-4334-ad23-f57d6f9c5ca3'	(b) (4), (b) (6) System	06 Aug 2020 21:57:38
User entered 'No (N)'	System	06 Aug 2020 21:57:38

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-06T17:57:34', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'daf67b49-6ab3-4334-ad23-f57d6f9c5ca3'	(b) (4), (b) (6) System	06 Aug 2020 21:57:38
User entered '06 Aug 2020 17:57'	System	06 Aug 2020 21:57:38

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 17:42'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 20:12'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6) System	06 Aug 2020 21:29:37
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:01:09', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a6dbc1b0-a7b1-4a23-a330-cbe7828b8eee'	(b) (4), (b) (6) System	07 Aug 2020 15:02:05
User entered 'None (0)'	System	07 Aug 2020 15:02:05

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:01:18', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a6dbc1b0-a7b1-4a23-a330-cbe7828b8eee'	(b) (4), (b) (6) System	07 Aug 2020 15:02:05
User entered 'None (0)'	System	07 Aug 2020 15:02:05

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:01:36', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a6dbc1b0-a7b1-4a23-a330-cbe7828b8eee'	(b) (4), (b) (6) System	07 Aug 2020 15:02:05
User entered 'None (0)'	System	07 Aug 2020 15:02:05

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:01:43', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a6dbc1b0-a7b1-4a23-a330-cbe7828b8eee'	(b) (4), (b) (6) System	07 Aug 2020 15:02:05
User entered 'None (0)'	System	07 Aug 2020 15:02:05

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:01:46', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a6dbc1b0-a7b1-4a23-a330-cbe7828b8eee'	(b) (4), (b) (6) System	07 Aug 2020 15:02:05
User entered 'None (0)'	System	07 Aug 2020 15:02:05

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:01:49', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a6dbc1b0-a7b1-4a23-a330-cbe7828b8eee'	(b) (4), (b) (6) System	07 Aug 2020 15:02:05
User entered 'None (0)'	System	07 Aug 2020 15:02:05

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:02:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a6dbc1b0-a7b1-4a23-a330-cbe7828b8eee'	(b) (4), (b) (6) System	07 Aug 2020 15:02:05
User entered 'No (N)'	System	07 Aug 2020 15:02:05

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-07T11:02:03', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a6dbc1b0-a7b1-4a23-a330-cbe7828b8eee'	(b) (4), (b) (6) System	07 Aug 2020 15:02:05
User entered '07 Aug 2020 11:02'	System	07 Aug 2020 15:02:05

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Aug 2020 21:07'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '304daea7-533c-4768-a448-e40186bda2fc'	(b) (4), (b) (6) System	08 Aug 2020 14:08:18
User entered 'None (0)'	System	08 Aug 2020 14:08:18

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:49', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '304daea7-533c-4768-a448-e40186bda2fc'	(b) (4), (b) (6) System	08 Aug 2020 14:08:18
User entered 'None (0)'	System	08 Aug 2020 14:08:18

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '304daea7-533c-4768-a448-e40186bda2fc'	(b) (4), (b) (6) System	08 Aug 2020 14:08:18
User entered 'None (0)'	System	08 Aug 2020 14:08:18

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:07:57', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '304daea7-533c-4768-a448-e40186bda2fc'	(b) (4), (b) (6) System	08 Aug 2020 14:08:18
User entered 'None (0)'	System	08 Aug 2020 14:08:18

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:08:03', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '304daea7-533c-4768-a448-e40186bda2fc'	(b) (4), (b) (6) System	08 Aug 2020 14:08:18
User entered 'None (0)'	System	08 Aug 2020 14:08:18

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:08:05', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '304daea7-533c-4768-a448-e40186bda2fc'	(b) (4), (b) (6) System	08 Aug 2020 14:08:18
User entered 'None (0)'	System	08 Aug 2020 14:08:18

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:08:09', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '304daea7-533c-4768-a448-e40186bda2fc'	(b) (4), (b) (6) System	08 Aug 2020 14:08:18
User entered 'No (N)'	System	08 Aug 2020 14:08:18

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-08T10:08:12', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '304daea7-533c-4768-a448-e40186bda2fc'	(b) (4), (b) (6) System	08 Aug 2020 14:08:18
User entered '08 Aug 2020 10:08'	System	08 Aug 2020 14:08:18

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:11', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ed127e6e-94f1-4a99-acaf-8364080fc182'	(b) (4), (b) (6) System	09 Aug 2020 05:52:30
User entered 'None (0)'	System	09 Aug 2020 05:52:30

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:14', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ed127e6e-94f1-4a99-acaf-8364080fc182'	(b) (4), (b) (6) System	09 Aug 2020 05:52:30
User entered 'None (0)'	System	09 Aug 2020 05:52:30

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:16', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ed127e6e-94f1-4a99-acaf-8364080fc182'	(b) (4), (b) (6) System	09 Aug 2020 05:52:30
User entered 'None (0)'	System	09 Aug 2020 05:52:30

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:18', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ed127e6e-94f1-4a99-acaf-8364080fc182'	(b) (4), (b) (6) System	09 Aug 2020 05:52:30
User entered 'None (0)'	System	09 Aug 2020 05:52:30

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:20', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ed127e6e-94f1-4a99-acaf-8364080fc182'	(b) (4), (b) (6) System	09 Aug 2020 05:52:30
User entered 'None (0)'	System	09 Aug 2020 05:52:30

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:22', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ed127e6e-94f1-4a99-acaf-8364080fc182'	(b) (4), (b) (6) System	09 Aug 2020 05:52:30
User entered 'None (0)'	System	09 Aug 2020 05:52:30

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:25', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ed127e6e-94f1-4a99-acaf-8364080fc182'	(b) (4), (b) (6) System	09 Aug 2020 05:52:30
User entered 'No (N)'	System	09 Aug 2020 05:52:30

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T01:52:27', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ed127e6e-94f1-4a99-acaf-8364080fc182'	(b) (4), (b) (6) System	09 Aug 2020 05:52:30
User entered '09 Aug 2020 01:52'	System	09 Aug 2020 05:52:30

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:55', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7912d6ed-d695-4688-89a6-f0b73cba08b4'	(b) (4), (b) (6) System	10 Aug 2020 02:25:13
User entered 'None (0)'	System	10 Aug 2020 02:25:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:57', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7912d6ed-d695-4688-89a6-f0b73cba08b4'	(b) (4), (b) (6) System	10 Aug 2020 02:25:13
User entered 'None (0)'	System	10 Aug 2020 02:25:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:24:59', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7912d6ed-d695-4688-89a6-f0b73cba08b4'	(b) (4), (b) (6) System	10 Aug 2020 02:25:13
User entered 'None (0)'	System	10 Aug 2020 02:25:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:25:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7912d6ed-d695-4688-89a6-f0b73cba08b4'	(b) (4), (b) (6) System	10 Aug 2020 02:25:13
User entered 'None (0)'	System	10 Aug 2020 02:25:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:25:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7912d6ed-d695-4688-89a6-f0b73cba08b4'	(b) (4), (b) (6) System	10 Aug 2020 02:25:13
User entered 'None (0)'	System	10 Aug 2020 02:25:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:25:05', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7912d6ed-d695-4688-89a6-f0b73cba08b4'	(b) (4), (b) (6) System	10 Aug 2020 02:25:13
User entered 'None (0)'	System	10 Aug 2020 02:25:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:25:08', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7912d6ed-d695-4688-89a6-f0b73cba08b4'	(b) (4), (b) (6) System	10 Aug 2020 02:25:13
User entered 'No (N)'	System	10 Aug 2020 02:25:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-09T22:25:10', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7912d6ed-d695-4688-89a6-f0b73cba08b4'	(b) (4), (b) (6) System	10 Aug 2020 02:25:13
User entered '09 Aug 2020 22:25'	System	10 Aug 2020 02:25:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 5'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:57', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dab6f8c0-d466-413f-bed6-f798ac4b803a'	(b) (4), (b) (6) System	11 Aug 2020 11:16:13
User entered 'None (0)'	System	11 Aug 2020 11:16:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:15:59', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dab6f8c0-d466-413f-bed6-f798ac4b803a'	(b) (4), (b) (6) System	11 Aug 2020 11:16:13
User entered 'None (0)'	System	11 Aug 2020 11:16:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:16:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dab6f8c0-d466-413f-bed6-f798ac4b803a'	(b) (4), (b) (6) System	11 Aug 2020 11:16:13
User entered 'None (0)'	System	11 Aug 2020 11:16:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:16:02', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dab6f8c0-d466-413f-bed6-f798ac4b803a'	(b) (4), (b) (6) System	11 Aug 2020 11:16:13
User entered 'None (0)'	System	11 Aug 2020 11:16:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:16:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dab6f8c0-d466-413f-bed6-f798ac4b803a'	(b) (4), (b) (6) System	11 Aug 2020 11:16:13
User entered 'None (0)'	System	11 Aug 2020 11:16:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:16:06', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dab6f8c0-d466-413f-bed6-f798ac4b803a'	(b) (4), (b) (6) System	11 Aug 2020 11:16:13
User entered 'None (0)'	System	11 Aug 2020 11:16:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:16:08', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dab6f8c0-d466-413f-bed6-f798ac4b803a'	(b) (4), (b) (6) System	11 Aug 2020 11:16:13
User entered 'No (N)'	System	11 Aug 2020 11:16:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-11T07:16:12', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dab6f8c0-d466-413f-bed6-f798ac4b803a'	(b) (4), (b) (6) System	11 Aug 2020 11:16:13
User entered '11 Aug 2020 07:16'	System	11 Aug 2020 11:16:13

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 6'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3583fad0-1fb4-42e2-9ac4-c50241baa5a6'	(b) (4), (b) (6) System	12 Aug 2020 14:04:58
User entered 'None (0)'	System	12 Aug 2020 14:04:58

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:50', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3583fad0-1fb4-42e2-9ac4-c50241baa5a6'	(b) (4), (b) (6) System	12 Aug 2020 14:04:58
User entered 'None (0)'	System	12 Aug 2020 14:04:58

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:52', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3583fad0-1fb4-42e2-9ac4-c50241baa5a6'	(b) (4), (b) (6) System	12 Aug 2020 14:04:58
User entered 'None (0)'	System	12 Aug 2020 14:04:58

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:55', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3583fad0-1fb4-42e2-9ac4-c50241baa5a6'	(b) (4), (b) (6) System	12 Aug 2020 14:04:58
User entered 'None (0)'	System	12 Aug 2020 14:04:58

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:56', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3583fad0-1fb4-42e2-9ac4-c50241baa5a6'	(b) (4), (b) (6) System	12 Aug 2020 14:04:58
User entered 'None (0)'	System	12 Aug 2020 14:04:58

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:19:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3583fad0-1fb4-42e2-9ac4-c50241baa5a6'	(b) (4), (b) (6) System	12 Aug 2020 14:04:58
User entered 'None (0)'	System	12 Aug 2020 14:04:58

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:20:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3583fad0-1fb4-42e2-9ac4-c50241baa5a6'	(b) (4), (b) (6) System	12 Aug 2020 14:04:58
User entered 'No (N)'	System	12 Aug 2020 14:04:58

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T09:20:05', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3583fad0-1fb4-42e2-9ac4-c50241baa5a6'	(b) (4), (b) (6) System	12 Aug 2020 14:04:58
User entered '12 Aug 2020 09:20'	System	12 Aug 2020 14:04:58

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 7'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:35', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '585f7d44-5f46-481b-8db1-869a2f6859a7'	(b) (4), (b) (6) System	13 Aug 2020 01:10:53
User entered 'None (0)'	System	13 Aug 2020 01:10:53

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:37', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '585f7d44-5f46-481b-8db1-869a2f6859a7'	(b) (4), (b) (6) System	13 Aug 2020 01:10:53
User entered 'None (0)'	System	13 Aug 2020 01:10:53

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:39', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '585f7d44-5f46-481b-8db1-869a2f6859a7'	(b) (4), (b) (6) System	13 Aug 2020 01:10:53
User entered 'None (0)'	System	13 Aug 2020 01:10:53

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:41', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '585f7d44-5f46-481b-8db1-869a2f6859a7'	(b) (4), (b) (6) System	13 Aug 2020 01:10:53
User entered 'None (0)'	System	13 Aug 2020 01:10:53

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:43', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '585f7d44-5f46-481b-8db1-869a2f6859a7'	(b) (4), (b) (6) System	13 Aug 2020 01:10:53
User entered 'None (0)'	System	13 Aug 2020 01:10:53

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:45', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '585f7d44-5f46-481b-8db1-869a2f6859a7'	(b) (4), (b) (6) System	13 Aug 2020 01:10:53
User entered 'None (0)'	System	13 Aug 2020 01:10:53

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '585f7d44-5f46-481b-8db1-869a2f6859a7'	(b) (4), (b) (6) System	13 Aug 2020 01:10:53
User entered 'No (N)'	System	13 Aug 2020 01:10:53

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-08-12T21:10:50', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '585f7d44-5f46-481b-8db1-869a2f6859a7'	(b) (4), (b) (6) System	13 Aug 2020 01:10:53
User entered '12 Aug 2020 21:10'	System	13 Aug 2020 01:10:53

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:49:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Aug 2020 22:07:39

US3242013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:49:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '14 Aug 2020'	Donna Toepfer (b) (4)	14 Aug 2020 22:07:39

US3242013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:49:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	14 Aug 2020 22:07:39

US3242013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:49:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Donna Toepfer (b) (4)	14 Aug 2020 22:07:39

US3242013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:49:13
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Aug 2020 22:07:31

US3242013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered 'I'	(b) (4), (b) (6) System	14 Aug 2020 22:07:31

US3242013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:55:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	21 Aug 2020 20:27:10

US3242013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:55:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '21 Aug 2020'	Grace Newville (b) (4) (b) (4)	21 Aug 2020 20:27:10

US3242013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:55:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4) (b) (4)	21 Aug 2020 20:27:10

US3242013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:55:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Grace Newville (b) (4) (b) (4)	21 Aug 2020 20:27:10

US3242013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:56:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	21 Aug 2020 20:27:03

US3242013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 20:27:03

US3242013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:53:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	28 Aug 2020 19:16:15

US3242013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:53:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered '28 Aug 2020'	Grace Newville (b) (4) (b) (4)	28 Aug 2020 19:16:15

US3242013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:53:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4) (b) (4)	28 Aug 2020 19:16:15

US3242013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:53:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered empty.	Grace Newville (b) (4) (b) (4)	28 Aug 2020 19:16:15

US3242013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 17:53:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	28 Aug 2020 19:16:08

US3242013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered 'I'	(b) (4), (b) (6) System	28 Aug 2020 19:16:08

US3242013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 20:27:06

US3242013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 20:27:06

US3242013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[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 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	03 Sep 2020 20:27:06

US3242013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'VISIT2'	System	03 Sep 2020 20:27:06

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered '03 Sep 2020'	(b) (4) Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered '15:37'	(b) (4) Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered '03 Sep 2020 15:37'	(b) (4), (b) (6) System	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '98.1' F	Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Oral (Oral)'	(b) (4) Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '68'	Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'bpm'	(b) (4), (b) (6) System	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '18'	Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'breaths/min'	System	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '118'	Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	System	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '70'	Donna Toepfer (b) (4)	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 14:35:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered '03 Sep 2020'	(b) (4) Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '17:07'	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered '03 Sep 2020 17:07'	(b) (4), (b) (6) System	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '98.0' F	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Oral (Oral)'	(b) (4) Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '62' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Oct 2020 14:36:37
User entered '124'	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'bpm'	System	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Oct 2020 14:36:37
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	01 Oct 2020 14:36:37
User entered '16' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Oct 2020 14:36:37
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Oct 2020 14:36:13
User entered '72'	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'breaths/min'	System	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Oct 2020 14:36:37
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	01 Oct 2020 14:36:37
User entered '124' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Oct 2020 14:36:37
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Oct 2020 14:36:13
User entered '62'	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Oct 2020 14:36:37
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	01 Oct 2020 14:36:37
User entered '72' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Oct 2020 14:36:37
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Oct 2020 14:36:13
User entered '16'	Donna Toepfer (b) (4)	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	System	01 Oct 2020 14:36:13

US3242013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Sep 2020 20:31:01
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 20:27:58

US3242013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 20:32:57
	(b) (4)	
User entered '3 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Sep 2020 20:31:01
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 20:27:58

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	(b) (4) Donna Toepfer (b) (4)	03 Sep 2020 20:28:17

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 20:33:10
	(b) (4)	
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 20:28:17

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Urine (URINE)'	Donna Toepfer (b) (4)	03 Sep 2020 20:28:17

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Donna Toepfer (b) (4)	03 Sep 2020 20:28:17

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	03 Sep 2020 20:28:17

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 20:28:17

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 20:28:17

US3242013

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 20:28:17

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	(b) (4) Donna Toepfer (b) (4)	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

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 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 20:33:34
	(b) (4)	
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '16:37'	Donna Toepfer (b) (4)	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User entered '03 Sep 2020 16:37'	System	19 Nov 2020 20:33:34
User entered '3 Sep 2020 16:37'	System	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) Donna Toepfer (b) (4)	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'ONCE'	System	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 20:47:36

US3242013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	(b) (4) Donna Toepfer (b) (4)	03 Sep 2020 20:30:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 20:33:45
	(b) (4)	
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 20:30:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '16:22'	Donna Toepfer (b) (4)	03 Sep 2020 20:30:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User entered '03 Sep 2020 16:22'	System	19 Nov 2020 20:33:45
User entered '3 Sep 2020 16:22'	System	03 Sep 2020 20:30:33

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:10:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 20:34:01
	(b) (4)	
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	(b) (4) Donna Toepfer (b) (4)	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '16:15'	Donna Toepfer (b) (4)	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User entered '03 Sep 2020 16:15'	System	19 Nov 2020 20:34:01
User entered '3 Sep 2020 16:15'	System	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 20:30:49

US3242013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 20:31:06

US3242013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered '1'	(b) (4), (b) (6) System	03 Sep 2020 20:31:06

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	03 Sep 2020 20:47:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:08:46', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3128dbe1-78df-40fd-8d4f-c30d65afcaea'	(b) (4), (b) (6) System	03 Sep 2020 21:09:03
User entered 'Yes (Y)'	System	03 Sep 2020 21:09:03

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:08:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3128dbe1-78df-40fd-8d4f-c30d65afcaea'	(b) (4), (b) (6) System	03 Sep 2020 21:09:03
User entered '97.7'	System	03 Sep 2020 21:09:03

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:08:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3128dbe1-78df-40fd-8d4f-c30d65afcaea'	(b) (4), (b) (6) System	03 Sep 2020 21:09:03
User entered 'No (N)'	System	03 Sep 2020 21:09:03

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3128dbe1-78df-40fd-8d4f-c30d65afcaea'	(b) (4), (b) (6) System	03 Sep 2020 21:09:03
User entered '03 Sep 2020 17:09'	System	03 Sep 2020 21:09:03

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 16:57'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 19:27'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
	System	03 Sep 2020 20:47:36
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:12:55', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e647a4a3-b7a5-4fdb-b3ca-8062d0b1b073'	(b) (4), (b) (6) System	04 Sep 2020 12:13:14
User entered 'Yes (Y)'	System	04 Sep 2020 12:13:14

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e647a4a3-b7a5-4fdb-b3ca-8062d0b1b073'	(b) (4), (b) (6) System	04 Sep 2020 12:13:14
User entered '97.9'	System	04 Sep 2020 12:13:14

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:09', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e647a4a3-b7a5-4fdb-b3ca-8062d0b1b073'	(b) (4), (b) (6) System	04 Sep 2020 12:13:14
User entered 'No (N)'	System	04 Sep 2020 12:13:14

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:13', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e647a4a3-b7a5-4fdb-b3ca-8062d0b1b073'	(b) (4), (b) (6) System	04 Sep 2020 12:13:14
User entered '04 Sep 2020 08:13'	System	04 Sep 2020 12:13:14

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 20:22'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:54:25', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f64860e2-eeff-460c-b961-a8f06d40d4d7'	(b) (4), (b) (6) System	05 Sep 2020 04:54:42
User entered 'Yes (Y)'	System	05 Sep 2020 04:54:42

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:54:33', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f64860e2-eeff-460c-b961-a8f06d40d4d7'	(b) (4), (b) (6) System	05 Sep 2020 04:54:42
User entered '98.3'	System	05 Sep 2020 04:54:42

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:54:36', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f64860e2-eeff-460c-b961-a8f06d40d4d7'	(b) (4), (b) (6) System	05 Sep 2020 04:54:42
User entered 'No (N)'	System	05 Sep 2020 04:54:42

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:54:40', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f64860e2-eeff-460c-b961-a8f06d40d4d7'	(b) (4), (b) (6) System	05 Sep 2020 04:54:42
User entered '05 Sep 2020 00:54'	System	05 Sep 2020 04:54:42

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94d9175e-ef02-4be1-9ef0-3915ddd4565d'	(b) (4), (b) (6) System	06 Sep 2020 10:03:53
User entered 'Yes (Y)'	System	06 Sep 2020 10:03:53

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:35', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94d9175e-ef02-4be1-9ef0-3915ddd4565d'	(b) (4), (b) (6) System	06 Sep 2020 10:03:53
User entered '98.5'	System	06 Sep 2020 10:03:53

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:38', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94d9175e-ef02-4be1-9ef0-3915ddd4565d'	(b) (4), (b) (6) System	06 Sep 2020 10:03:53
User entered 'No (N)'	System	06 Sep 2020 10:03:53

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:44', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94d9175e-ef02-4be1-9ef0-3915ddd4565d'	(b) (4), (b) (6) System	06 Sep 2020 10:03:53
User entered '06 Sep 2020 06:03'	System	06 Sep 2020 10:03:53

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:17:36', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '120d12be-3c71-4dcd-ad88-4e06f2bbbe13'	(b) (4), (b) (6) System	07 Sep 2020 12:18:12
User entered 'Yes (Y)'	System	07 Sep 2020 12:18:12

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:17:49', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '120d12be-3c71-4dcd-ad88-4e06f2bbbe13'	(b) (4), (b) (6) System	07 Sep 2020 12:18:12
User entered '97.1'	System	07 Sep 2020 12:18:12

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:17:53', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '120d12be-3c71-4dcd-ad88-4e06f2bbbe13'	(b) (4), (b) (6) System	07 Sep 2020 12:18:12
User entered 'No (N)'	System	07 Sep 2020 12:18:12

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:17:55', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '120d12be-3c71-4dcd-ad88-4e06f2bbbe13'	(b) (4), (b) (6) System	07 Sep 2020 12:18:12
User entered '07 Sep 2020 08:17'	System	07 Sep 2020 12:18:12

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 5'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:51:39', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3f10387c-3546-4464-9be0-26234ff6bf56'	(b) (4), (b) (6) System	08 Sep 2020 09:52:00
User entered 'Yes (Y)'	System	08 Sep 2020 09:52:00

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:51:44', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3f10387c-3546-4464-9be0-26234ff6bf56'	(b) (4), (b) (6) System	08 Sep 2020 09:52:00
User entered '98.2'	System	08 Sep 2020 09:52:00

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:51:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3f10387c-3546-4464-9be0-26234ff6bf56'	(b) (4), (b) (6) System	08 Sep 2020 09:52:00
User entered 'No (N)'	System	08 Sep 2020 09:52:00

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:51:57', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '3f10387c-3546-4464-9be0-26234ff6bf56'	(b) (4), (b) (6) System	08 Sep 2020 09:52:00
User entered '08 Sep 2020 05:51'	System	08 Sep 2020 09:52:00

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
	System	03 Sep 2020 20:47:36
User entered 'Day 6'	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:16:35', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'b757f2de-ff38-4cf6-a8c5-fd4210fd9c0e'	(b) (4), (b) (6) System	09 Sep 2020 01:17:00
User entered 'Yes (Y)'	System	09 Sep 2020 01:17:00

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:16:46', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'b757f2de-ff38-4cf6-a8c5-fd4210fd9c0e'	(b) (4), (b) (6) System	09 Sep 2020 01:17:00
User entered '97.7'	System	09 Sep 2020 01:17:00

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:16:49', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'b757f2de-ff38-4cf6-a8c5-fd4210fd9c0e'	(b) (4), (b) (6) System	09 Sep 2020 01:17:00
User entered 'No (N)'	System	09 Sep 2020 01:17:00

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:16:55', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'b757f2de-ff38-4cf6-a8c5-fd4210fd9c0e'	(b) (4), (b) (6) System	09 Sep 2020 01:17:00
User entered '08 Sep 2020 21:16'	System	09 Sep 2020 01:17:00

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 7'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:36:30', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '80185d8d-568e-4b6f-8fff-4e2b3d07f99b'	(b) (4), (b) (6) System	10 Sep 2020 12:36:55
User entered 'Yes (Y)'	System	10 Sep 2020 12:36:55

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:36:40', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '80185d8d-568e-4b6f-8fff-4e2b3d07f99b'	(b) (4), (b) (6) System	10 Sep 2020 12:36:55
User entered '98.5'	System	10 Sep 2020 12:36:55

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:36:44', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '80185d8d-568e-4b6f-8fff-4e2b3d07f99b'	(b) (4), (b) (6) System	10 Sep 2020 12:36:55
User entered 'No (N)'	System	10 Sep 2020 12:36:55

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:36:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '80185d8d-568e-4b6f-8fff-4e2b3d07f99b'	(b) (4), (b) (6) System	10 Sep 2020 12:36:55
User entered '10 Sep 2020 08:36'	System	10 Sep 2020 12:36:55

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:10', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '567f2ad8-2dc0-4572-9220-d3632314ca28'	(b) (4), (b) (6) System	03 Sep 2020 21:09:53
User entered 'None (1)'	System	03 Sep 2020 21:09:53

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '567f2ad8-2dc0-4572-9220-d3632314ca28'	(b) (4), (b) (6) System	03 Sep 2020 21:09:53
User entered 'No (N)'	System	03 Sep 2020 21:09:53

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:28', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '567f2ad8-2dc0-4572-9220-d3632314ca28'	(b) (4), (b) (6) System	03 Sep 2020 21:09:53
User entered 'No (N)'	System	03 Sep 2020 21:09:53

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:34', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '567f2ad8-2dc0-4572-9220-d3632314ca28'	(b) (4), (b) (6) System	03 Sep 2020 21:09:53
User entered 'None (1)'	System	03 Sep 2020 21:09:53

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:49', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '567f2ad8-2dc0-4572-9220-d3632314ca28'	(b) (4), (b) (6) System	03 Sep 2020 21:09:53
User entered '03 Sep 2020 17:09'	System	03 Sep 2020 21:09:53

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 16:57'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 19:27'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6) System	03 Sep 2020 20:47:36
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c514c3e7-1499-46b2-a6fb-f44f8307e9d6'	(b) (4), (b) (6) System	04 Sep 2020 12:13:36
User entered 'None (1)'	System	04 Sep 2020 12:13:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:24', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c514c3e7-1499-46b2-a6fb-f44f8307e9d6'	(b) (4), (b) (6) System	04 Sep 2020 12:13:36
User entered 'No (N)'	System	04 Sep 2020 12:13:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:26', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c514c3e7-1499-46b2-a6fb-f44f8307e9d6'	(b) (4), (b) (6) System	04 Sep 2020 12:13:36
User entered 'No (N)'	System	04 Sep 2020 12:13:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:28', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c514c3e7-1499-46b2-a6fb-f44f8307e9d6'	(b) (4), (b) (6) System	04 Sep 2020 12:13:36
User entered 'None (1)'	System	04 Sep 2020 12:13:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:31', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c514c3e7-1499-46b2-a6fb-f44f8307e9d6'	(b) (4), (b) (6) System	04 Sep 2020 12:13:36
User entered '04 Sep 2020 08:13'	System	04 Sep 2020 12:13:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 20:22'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:54:51', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1421385b-6752-4738-b378-11789197215d'	(b) (4), (b) (6) System	05 Sep 2020 04:55:24
User entered 'None (1)'	System	05 Sep 2020 04:55:24

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:54:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1421385b-6752-4738-b378-11789197215d'	(b) (4), (b) (6) System	05 Sep 2020 04:55:24
User entered 'No (N)'	System	05 Sep 2020 04:55:24

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:54:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1421385b-6752-4738-b378-11789197215d'	(b) (4), (b) (6) System	05 Sep 2020 04:55:24
User entered 'No (N)'	System	05 Sep 2020 04:55:24

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:03', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1421385b-6752-4738-b378-11789197215d'	(b) (4), (b) (6) System	05 Sep 2020 04:55:24
User entered 'None (1)'	System	05 Sep 2020 04:55:24

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:19', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '1421385b-6752-4738-b378-11789197215d'	(b) (4), (b) (6) System	05 Sep 2020 04:55:24
User entered '05 Sep 2020 00:55'	System	05 Sep 2020 04:55:24

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:48', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'd7702ede-4d05-4277-8fca-e056e6eb5ee2'	(b) (4), (b) (6) System	06 Sep 2020 10:04:02
User entered 'None (1)'	System	06 Sep 2020 10:04:02

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:50', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'd7702ede-4d05-4277-8fca-e056e6eb5ee2'	(b) (4), (b) (6) System	06 Sep 2020 10:04:02
User entered 'No (N)'	System	06 Sep 2020 10:04:02

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:52', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'd7702ede-4d05-4277-8fca-e056e6eb5ee2'	(b) (4), (b) (6) System	06 Sep 2020 10:04:02
User entered 'No (N)'	System	06 Sep 2020 10:04:02

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'd7702ede-4d05-4277-8fca-e056e6eb5ee2'	(b) (4), (b) (6) System	06 Sep 2020 10:04:02
User entered 'None (1)'	System	06 Sep 2020 10:04:02

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:56', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'd7702ede-4d05-4277-8fca-e056e6eb5ee2'	(b) (4), (b) (6) System	06 Sep 2020 10:04:02
User entered '06 Sep 2020 06:03'	System	06 Sep 2020 10:04:02

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:02', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '25bde11b-779b-40c4-baac-3da65393dd10'	(b) (4), (b) (6) System	07 Sep 2020 12:18:26
User entered 'None (1)'	System	07 Sep 2020 12:18:26

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '25bde11b-779b-40c4-baac-3da65393dd10'	(b) (4), (b) (6) System	07 Sep 2020 12:18:26
User entered 'No (N)'	System	07 Sep 2020 12:18:26

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:08', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '25bde11b-779b-40c4-baac-3da65393dd10'	(b) (4), (b) (6) System	07 Sep 2020 12:18:26
User entered 'No (N)'	System	07 Sep 2020 12:18:26

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:10', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '25bde11b-779b-40c4-baac-3da65393dd10'	(b) (4), (b) (6) System	07 Sep 2020 12:18:26
User entered 'None (1)'	System	07 Sep 2020 12:18:26

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:12', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '25bde11b-779b-40c4-baac-3da65393dd10'	(b) (4), (b) (6) System	07 Sep 2020 12:18:26
User entered '07 Sep 2020 08:18'	System	07 Sep 2020 12:18:26

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 5'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:02', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5a0b474d-f1fa-4851-81ac-1d933c9082c9'	(b) (4), (b) (6) System	08 Sep 2020 09:52:16
User entered 'None (1)'	System	08 Sep 2020 09:52:16

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:05', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5a0b474d-f1fa-4851-81ac-1d933c9082c9'	(b) (4), (b) (6) System	08 Sep 2020 09:52:16
User entered 'No (N)'	System	08 Sep 2020 09:52:16

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:08', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5a0b474d-f1fa-4851-81ac-1d933c9082c9'	(b) (4), (b) (6) System	08 Sep 2020 09:52:16
User entered 'No (N)'	System	08 Sep 2020 09:52:16

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:10', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5a0b474d-f1fa-4851-81ac-1d933c9082c9'	(b) (4), (b) (6) System	08 Sep 2020 09:52:16
User entered 'None (1)'	System	08 Sep 2020 09:52:16

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:14', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5a0b474d-f1fa-4851-81ac-1d933c9082c9'	(b) (4), (b) (6) System	08 Sep 2020 09:52:16
User entered '08 Sep 2020 05:52'	System	08 Sep 2020 09:52:16

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 6'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:16:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94e2ae51-be7b-423f-adc9-a46c95d3c871'	(b) (4), (b) (6) System	09 Sep 2020 01:17:09
User entered 'None (1)'	System	09 Sep 2020 01:17:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94e2ae51-be7b-423f-adc9-a46c95d3c871'	(b) (4), (b) (6) System	09 Sep 2020 01:17:09
User entered 'No (N)'	System	09 Sep 2020 01:17:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:02', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94e2ae51-be7b-423f-adc9-a46c95d3c871'	(b) (4), (b) (6) System	09 Sep 2020 01:17:09
User entered 'No (N)'	System	09 Sep 2020 01:17:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94e2ae51-be7b-423f-adc9-a46c95d3c871'	(b) (4), (b) (6) System	09 Sep 2020 01:17:09
User entered 'None (1)'	System	09 Sep 2020 01:17:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:07', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '94e2ae51-be7b-423f-adc9-a46c95d3c871'	(b) (4), (b) (6) System	09 Sep 2020 01:17:09
User entered '08 Sep 2020 21:17'	System	09 Sep 2020 01:17:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 7'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:36:51', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dbf3f865-85dd-489e-907f-e2b655e3b925'	(b) (4), (b) (6) System	10 Sep 2020 12:37:09
User entered 'None (1)'	System	10 Sep 2020 12:37:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:36:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dbf3f865-85dd-489e-907f-e2b655e3b925'	(b) (4), (b) (6) System	10 Sep 2020 12:37:09
User entered 'No (N)'	System	10 Sep 2020 12:37:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:36:56', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dbf3f865-85dd-489e-907f-e2b655e3b925'	(b) (4), (b) (6) System	10 Sep 2020 12:37:09
User entered 'No (N)'	System	10 Sep 2020 12:37:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:36:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dbf3f865-85dd-489e-907f-e2b655e3b925'	(b) (4), (b) (6) System	10 Sep 2020 12:37:09
User entered 'None (1)'	System	10 Sep 2020 12:37:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:02', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'dbf3f865-85dd-489e-907f-e2b655e3b925'	(b) (4), (b) (6) System	10 Sep 2020 12:37:09
User entered '10 Sep 2020 08:37'	System	10 Sep 2020 12:37:09

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:55', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c40138e6-6b9c-4e26-9098-4d6f4e67af43'	(b) (4), (b) (6) System	03 Sep 2020 21:10:57
User entered 'None (0)'	System	03 Sep 2020 21:10:57

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:57', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c40138e6-6b9c-4e26-9098-4d6f4e67af43'	(b) (4), (b) (6) System	03 Sep 2020 21:10:57
User entered 'None (0)'	System	03 Sep 2020 21:10:57

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:09:59', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c40138e6-6b9c-4e26-9098-4d6f4e67af43'	(b) (4), (b) (6) System	03 Sep 2020 21:10:57
User entered 'None (0)'	System	03 Sep 2020 21:10:57

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:10:02', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c40138e6-6b9c-4e26-9098-4d6f4e67af43'	(b) (4), (b) (6) System	03 Sep 2020 21:10:57
User entered 'None (0)'	System	03 Sep 2020 21:10:57

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:10:32', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c40138e6-6b9c-4e26-9098-4d6f4e67af43'	(b) (4), (b) (6) System	03 Sep 2020 21:10:57
User entered 'None (0)'	System	03 Sep 2020 21:10:57

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:10:38', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c40138e6-6b9c-4e26-9098-4d6f4e67af43'	(b) (4), (b) (6) System	03 Sep 2020 21:10:57
User entered 'None (0)'	System	03 Sep 2020 21:10:57

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:10:45', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c40138e6-6b9c-4e26-9098-4d6f4e67af43'	(b) (4), (b) (6) System	03 Sep 2020 21:10:57
User entered 'No (N)'	System	03 Sep 2020 21:10:57

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-03T17:10:53', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c40138e6-6b9c-4e26-9098-4d6f4e67af43'	(b) (4), (b) (6) System	03 Sep 2020 21:10:57
User entered '03 Sep 2020 17:10'	System	03 Sep 2020 21:10:57

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 16:57'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 19:27'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
	System	03 Sep 2020 20:47:36
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:35', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '68007c2e-e0c3-4450-81a0-06cc04ea6545'	(b) (4), (b) (6) System	04 Sep 2020 12:13:52
User entered 'None (0)'	System	04 Sep 2020 12:13:52

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:36', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '68007c2e-e0c3-4450-81a0-06cc04ea6545'	(b) (4), (b) (6) System	04 Sep 2020 12:13:52
User entered 'None (0)'	System	04 Sep 2020 12:13:52

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:38', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '68007c2e-e0c3-4450-81a0-06cc04ea6545'	(b) (4), (b) (6) System	04 Sep 2020 12:13:52
User entered 'None (0)'	System	04 Sep 2020 12:13:52

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:40', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '68007c2e-e0c3-4450-81a0-06cc04ea6545'	(b) (4), (b) (6) System	04 Sep 2020 12:13:52
User entered 'None (0)'	System	04 Sep 2020 12:13:52

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:42', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '68007c2e-e0c3-4450-81a0-06cc04ea6545'	(b) (4), (b) (6) System	04 Sep 2020 12:13:52
User entered 'None (0)'	System	04 Sep 2020 12:13:52

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:44', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '68007c2e-e0c3-4450-81a0-06cc04ea6545'	(b) (4), (b) (6) System	04 Sep 2020 12:13:52
User entered 'None (0)'	System	04 Sep 2020 12:13:52

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:45', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '68007c2e-e0c3-4450-81a0-06cc04ea6545'	(b) (4), (b) (6) System	04 Sep 2020 12:13:52
User entered 'No (N)'	System	04 Sep 2020 12:13:52

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-04T08:13:48', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '68007c2e-e0c3-4450-81a0-06cc04ea6545'	(b) (4), (b) (6) System	04 Sep 2020 12:13:52
User entered '04 Sep 2020 08:13'	System	04 Sep 2020 12:13:52

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '03 Sep 2020 20:22'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:23', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2a74bb4-c3e2-48d1-a3a7-f81cc4e16fb2'	(b) (4), (b) (6) System	05 Sep 2020 04:55:46
User entered 'None (0)'	System	05 Sep 2020 04:55:46

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:25', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2a74bb4-c3e2-48d1-a3a7-f81cc4e16fb2'	(b) (4), (b) (6) System	05 Sep 2020 04:55:46
User entered 'None (0)'	System	05 Sep 2020 04:55:46

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:27', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2a74bb4-c3e2-48d1-a3a7-f81cc4e16fb2'	(b) (4), (b) (6) System	05 Sep 2020 04:55:46
User entered 'None (0)'	System	05 Sep 2020 04:55:46

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:29', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2a74bb4-c3e2-48d1-a3a7-f81cc4e16fb2'	(b) (4), (b) (6) System	05 Sep 2020 04:55:46
User entered 'None (0)'	System	05 Sep 2020 04:55:46

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:33', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2a74bb4-c3e2-48d1-a3a7-f81cc4e16fb2'	(b) (4), (b) (6) System	05 Sep 2020 04:55:46
User entered 'None (0)'	System	05 Sep 2020 04:55:46

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:35', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2a74bb4-c3e2-48d1-a3a7-f81cc4e16fb2'	(b) (4), (b) (6) System	05 Sep 2020 04:55:46
User entered 'None (0)'	System	05 Sep 2020 04:55:46

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:37', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2a74bb4-c3e2-48d1-a3a7-f81cc4e16fb2'	(b) (4), (b) (6) System	05 Sep 2020 04:55:46
User entered 'No (N)'	System	05 Sep 2020 04:55:46

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-05T00:55:43', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2a74bb4-c3e2-48d1-a3a7-f81cc4e16fb2'	(b) (4), (b) (6) System	05 Sep 2020 04:55:46
User entered '05 Sep 2020 00:55'	System	05 Sep 2020 04:55:46

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:03:59', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '802e4503-63d2-4953-8e69-12b04fe936a5'	(b) (4), (b) (6) System	06 Sep 2020 10:04:15
User entered 'None (0)'	System	06 Sep 2020 10:04:15

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:04:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '802e4503-63d2-4953-8e69-12b04fe936a5'	(b) (4), (b) (6) System	06 Sep 2020 10:04:15
User entered 'None (0)'	System	06 Sep 2020 10:04:15

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:04:03', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '802e4503-63d2-4953-8e69-12b04fe936a5'	(b) (4), (b) (6) System	06 Sep 2020 10:04:15
User entered 'None (0)'	System	06 Sep 2020 10:04:15

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:04:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '802e4503-63d2-4953-8e69-12b04fe936a5'	(b) (4), (b) (6) System	06 Sep 2020 10:04:15
User entered 'None (0)'	System	06 Sep 2020 10:04:15

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:04:06', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '802e4503-63d2-4953-8e69-12b04fe936a5'	(b) (4), (b) (6) System	06 Sep 2020 10:04:15
User entered 'None (0)'	System	06 Sep 2020 10:04:15

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:04:07', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '802e4503-63d2-4953-8e69-12b04fe936a5'	(b) (4), (b) (6) System	06 Sep 2020 10:04:15
User entered 'None (0)'	System	06 Sep 2020 10:04:15

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:04:09', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '802e4503-63d2-4953-8e69-12b04fe936a5'	(b) (4), (b) (6) System	06 Sep 2020 10:04:15
User entered 'No (N)'	System	06 Sep 2020 10:04:15

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-06T06:04:14', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '802e4503-63d2-4953-8e69-12b04fe936a5'	(b) (4), (b) (6) System	06 Sep 2020 10:04:15
User entered '06 Sep 2020 06:04'	System	06 Sep 2020 10:04:15

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:16', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '71b7be2b-4761-49fb-989f-ca527d8dd913'	(b) (4), (b) (6) System	07 Sep 2020 12:18:33
User entered 'None (0)'	System	07 Sep 2020 12:18:33

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:17', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '71b7be2b-4761-49fb-989f-ca527d8dd913'	(b) (4), (b) (6) System	07 Sep 2020 12:18:33
User entered 'None (0)'	System	07 Sep 2020 12:18:33

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:19', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '71b7be2b-4761-49fb-989f-ca527d8dd913'	(b) (4), (b) (6) System	07 Sep 2020 12:18:33
User entered 'None (0)'	System	07 Sep 2020 12:18:33

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '71b7be2b-4761-49fb-989f-ca527d8dd913'	(b) (4), (b) (6) System	07 Sep 2020 12:18:33
User entered 'None (0)'	System	07 Sep 2020 12:18:33

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:23', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '71b7be2b-4761-49fb-989f-ca527d8dd913'	(b) (4), (b) (6) System	07 Sep 2020 12:18:33
User entered 'None (0)'	System	07 Sep 2020 12:18:33

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:25', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '71b7be2b-4761-49fb-989f-ca527d8dd913'	(b) (4), (b) (6) System	07 Sep 2020 12:18:33
User entered 'None (0)'	System	07 Sep 2020 12:18:33

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:27', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '71b7be2b-4761-49fb-989f-ca527d8dd913'	(b) (4), (b) (6) System	07 Sep 2020 12:18:33
User entered 'No (N)'	System	07 Sep 2020 12:18:33

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-07T08:18:29', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '71b7be2b-4761-49fb-989f-ca527d8dd913'	(b) (4), (b) (6) System	07 Sep 2020 12:18:33
User entered '07 Sep 2020 08:18'	System	07 Sep 2020 12:18:33

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 5'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:18', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f1450777-98ea-4697-9649-65c27f140736'	(b) (4), (b) (6) System	08 Sep 2020 09:52:44
User entered 'None (0)'	System	08 Sep 2020 09:52:44

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:20', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f1450777-98ea-4697-9649-65c27f140736'	(b) (4), (b) (6) System	08 Sep 2020 09:52:44
User entered 'None (0)'	System	08 Sep 2020 09:52:44

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:22', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f1450777-98ea-4697-9649-65c27f140736'	(b) (4), (b) (6) System	08 Sep 2020 09:52:44
User entered 'None (0)'	System	08 Sep 2020 09:52:44

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:24', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f1450777-98ea-4697-9649-65c27f140736'	(b) (4), (b) (6) System	08 Sep 2020 09:52:44
User entered 'None (0)'	System	08 Sep 2020 09:52:44

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:26', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f1450777-98ea-4697-9649-65c27f140736'	(b) (4), (b) (6) System	08 Sep 2020 09:52:44
User entered 'None (0)'	System	08 Sep 2020 09:52:44

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:29', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f1450777-98ea-4697-9649-65c27f140736'	(b) (4), (b) (6) System	08 Sep 2020 09:52:44
User entered 'None (0)'	System	08 Sep 2020 09:52:44

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:31', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f1450777-98ea-4697-9649-65c27f140736'	(b) (4), (b) (6) System	08 Sep 2020 09:52:44
User entered 'No (N)'	System	08 Sep 2020 09:52:44

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T05:52:40', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f1450777-98ea-4697-9649-65c27f140736'	(b) (4), (b) (6) System	08 Sep 2020 09:52:44
User entered '08 Sep 2020 05:52'	System	08 Sep 2020 09:52:44

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 6'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:11', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '73d70930-1e84-45e3-8154-8ac6f1411de2'	(b) (4), (b) (6) System	09 Sep 2020 01:17:28
User entered 'None (0)'	System	09 Sep 2020 01:17:28

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:13', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '73d70930-1e84-45e3-8154-8ac6f1411de2'	(b) (4), (b) (6) System	09 Sep 2020 01:17:28
User entered 'None (0)'	System	09 Sep 2020 01:17:28

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:15', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '73d70930-1e84-45e3-8154-8ac6f1411de2'	(b) (4), (b) (6) System	09 Sep 2020 01:17:28
User entered 'None (0)'	System	09 Sep 2020 01:17:28

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:17', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '73d70930-1e84-45e3-8154-8ac6f1411de2'	(b) (4), (b) (6) System	09 Sep 2020 01:17:28
User entered 'None (0)'	System	09 Sep 2020 01:17:28

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:19', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '73d70930-1e84-45e3-8154-8ac6f1411de2'	(b) (4), (b) (6) System	09 Sep 2020 01:17:28
User entered 'None (0)'	System	09 Sep 2020 01:17:28

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:22', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '73d70930-1e84-45e3-8154-8ac6f1411de2'	(b) (4), (b) (6) System	09 Sep 2020 01:17:28
User entered 'None (0)'	System	09 Sep 2020 01:17:28

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:24', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '73d70930-1e84-45e3-8154-8ac6f1411de2'	(b) (4), (b) (6) System	09 Sep 2020 01:17:28
User entered 'No (N)'	System	09 Sep 2020 01:17:28

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-08T21:17:26', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '73d70930-1e84-45e3-8154-8ac6f1411de2'	(b) (4), (b) (6) System	09 Sep 2020 01:17:28
User entered '08 Sep 2020 21:17'	System	09 Sep 2020 01:17:28

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 7'	System	03 Sep 2020 20:47:36
	System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:08', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '86e52bdd-7196-48ba-9fdf-41cdc8db5294'	(b) (4), (b) (6) System	10 Sep 2020 12:37:35
User entered 'None (0)'	System	10 Sep 2020 12:37:35

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:10', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '86e52bdd-7196-48ba-9fdf-41cdc8db5294'	(b) (4), (b) (6) System	10 Sep 2020 12:37:35
User entered 'None (0)'	System	10 Sep 2020 12:37:35

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:11', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '86e52bdd-7196-48ba-9fdf-41cdc8db5294'	(b) (4), (b) (6) System	10 Sep 2020 12:37:35
User entered 'None (0)'	System	10 Sep 2020 12:37:35

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:13', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '86e52bdd-7196-48ba-9fdf-41cdc8db5294'	(b) (4), (b) (6) System	10 Sep 2020 12:37:35
User entered 'None (0)'	System	10 Sep 2020 12:37:35

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:15', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '86e52bdd-7196-48ba-9fdf-41cdc8db5294'	(b) (4), (b) (6) System	10 Sep 2020 12:37:35
User entered 'None (0)'	System	10 Sep 2020 12:37:35

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:17', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '86e52bdd-7196-48ba-9fdf-41cdc8db5294'	(b) (4), (b) (6) System	10 Sep 2020 12:37:35
User entered 'None (0)'	System	10 Sep 2020 12:37:35

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '86e52bdd-7196-48ba-9fdf-41cdc8db5294'	(b) (4), (b) (6) System	10 Sep 2020 12:37:35
User entered 'No (N)'	System	10 Sep 2020 12:37:35

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-09-10T08:37:24', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '86e52bdd-7196-48ba-9fdf-41cdc8db5294'	(b) (4), (b) (6) System	10 Sep 2020 12:37:35
User entered '10 Sep 2020 08:37'	System	10 Sep 2020 12:37:35

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 20:47:36

US3242013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:34:44

US3242013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:34:44

US3242013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 18:34:44

US3242013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:34:44

US3242013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:34:48

US3242013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered 'I'	(b) (4), (b) (6) System	11 Sep 2020 18:34:48

US3242013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	18 Sep 2020 19:02:53

US3242013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '18 Sep 2020'	Grace Newville (b) (4)	18 Sep 2020 19:02:53
	(b) (4)	

US3242013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	18 Sep 2020 19:02:53
	(b) (4)	

US3242013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Grace Newville (b) (4)	18 Sep 2020 19:02:53
	(b) (4)	

US3242013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	18 Sep 2020 19:02:57
	(b) (4)	

US3242013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered 'I'	System	18 Sep 2020 19:02:57

US3242013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	25 Sep 2020 18:31:44

US3242013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '25 Sep 2020'	Grace Newville (b) (4)	25 Sep 2020 18:31:44
	(b) (4)	

US3242013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	25 Sep 2020 18:31:44
	(b) (4)	

US3242013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Grace Newville (b) (4)	25 Sep 2020 18:31:44
	(b) (4)	

US3242013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	25 Sep 2020 18:31:47
	(b) (4)	

US3242013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered 'I'	System	25 Sep 2020 18:31:47

US3242013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	(b) (4) Donna Toepfer (b) (4)	01 Oct 2020 19:45:38

US3242013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '01 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 20:35:10
	(b) (4)	
User entered '1 Oct 2020'	Donna Toepfer (b) (4)	01 Oct 2020 19:45:38

US3242013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[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 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	01 Oct 2020 19:45:38

US3242013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'VISIT3'	System	01 Oct 2020 19:45:38

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	(b) (4) Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '01 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 20:35:28
	(b) (4)	
User entered '1 Oct 2020'	Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '15:15'	Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User entered '01 Oct 2020 15:15'	System	19 Nov 2020 20:35:28
User entered '1 Oct 2020 15:15'	System	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '97.9' F	Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
User entered '72'	(b) (4) Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'bpm'	System	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '19'	Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'breaths/min'	System	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '100'	Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	System	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '70'	Donna Toepfer (b) (4)	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered 'mmHg'	System	01 Oct 2020 19:46:09

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	

US3242013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	

US3242013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 19:46:18

US3242013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 19:46:18

US3242013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 20:05:14

US3242013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '01 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 20:35:43
	(b) (4)	
User entered '1 Oct 2020'	Donna Toepfer (b) (4)	01 Oct 2020 20:05:14

US3242013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '15:31'	Donna Toepfer (b) (4)	01 Oct 2020 20:05:14

US3242013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User entered '01 Oct 2020 15:31'	System	19 Nov 2020 20:35:43
User entered '1 Oct 2020 15:31'	System	01 Oct 2020 20:05:14

US3242013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 19:46:24

US3242013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:15
User entered '1'	(b) (4), (b) (6) System	01 Oct 2020 19:46:24

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 64'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-06T18:52:41', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'fe606224-9ac8-4fcf-88ed-14aea3a73f43'	(b) (4), (b) (6) System	06 Oct 2020 22:52:54
User entered 'No (N)'	System	06 Oct 2020 22:52:54

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-06T18:52:50', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'fe606224-9ac8-4fcf-88ed-14aea3a73f43'	(b) (4), (b) (6) System	06 Oct 2020 22:52:54
User entered 'No (N)'	System	06 Oct 2020 22:52:54

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-06T18:52:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'fe606224-9ac8-4fcf-88ed-14aea3a73f43'	(b) (4), (b) (6) System	06 Oct 2020 22:52:54
User entered '06 Oct 2020 18:52:54'	System	06 Oct 2020 22:52:54

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 21:29:37
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 21:29:37
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 71'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-14T07:50:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '9d2c59d4-b93c-4396-923d-0336cb6dea95'	(b) (4), (b) (6) System	15 Oct 2020 13:03:05
User entered 'No (N)'	System	15 Oct 2020 13:03:05

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-14T07:51:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '9d2c59d4-b93c-4396-923d-0336cb6dea95'	(b) (4), (b) (6) System	15 Oct 2020 13:03:05
User entered 'No (N)'	System	15 Oct 2020 13:03:05

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-14T07:51:24', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '9d2c59d4-b93c-4396-923d-0336cb6dea95'	(b) (4), (b) (6) System	15 Oct 2020 13:03:05
User entered '14 Oct 2020 07:51:24'	System	15 Oct 2020 13:03:05

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 78'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-21T17:51:52', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '0375a773-4cc2-43d3-861f-3bbbb695af29'	(b) (4), (b) (6) System	21 Oct 2020 21:52:04
User entered 'No (N)'	System	21 Oct 2020 21:52:04

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-21T17:52:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '0375a773-4cc2-43d3-861f-3bbbb695af29'	(b) (4), (b) (6) System	21 Oct 2020 21:52:04
User entered 'No (N)'	System	21 Oct 2020 21:52:04

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-10-21T17:52:03', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '0375a773-4cc2-43d3-861f-3bbbb695af29' User entered '21 Oct 2020 17:52:03'	(b) (4), (b) (6) System	21 Oct 2020 21:52:04
	System	21 Oct 2020 21:52:04

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 92'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-05T09:35:56', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '637c1e7e-41f3-4467-967a-abfcdd6e1f14'	(b) (4), (b) (6) System	05 Nov 2020 14:36:06
User entered 'No (N)'	System	05 Nov 2020 14:36:06

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-05T09:36:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '637c1e7e-41f3-4467-967a-abfcdd6e1f14'	(b) (4), (b) (6) System	05 Nov 2020 14:36:06
User entered 'No (N)'	System	05 Nov 2020 14:36:06

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-05T09:36:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '637c1e7e-41f3-4467-967a-abfcdd6e1f14' User entered '05 Nov 2020 09:36:04'	(b) (4), (b) (6) System	05 Nov 2020 14:36:06
	System	05 Nov 2020 14:36:06

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
	System	06 Aug 2020 21:29:37
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 21:29:37
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 99'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-10T15:34:39', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f09d8ba6-0bbf-498e-9997-1316b1688dbe'	(b) (4), (b) (6) System	10 Nov 2020 20:34:55
User entered 'No (N)'	System	10 Nov 2020 20:34:55

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-10T15:34:50', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f09d8ba6-0bbf-498e-9997-1316b1688dbe'	(b) (4), (b) (6) System	10 Nov 2020 20:34:55
User entered 'No (N)'	System	10 Nov 2020 20:34:55

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-10T15:34:52', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'f09d8ba6-0bbf-498e-9997-1316b1688dbe' User entered '10 Nov 2020 15:34:52'	(b) (4), (b) (6) System	10 Nov 2020 20:34:55
	System	10 Nov 2020 20:34:55

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
	System	06 Aug 2020 21:29:37
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
	(b) (4), (b) (6)	
Data entry locked.	System	06 Aug 2020 21:29:37
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 106'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-17T11:34:08', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5f7f7e36-9bb7-4da0-9186-c7d728290102'	(b) (4), (b) (6) System	17 Nov 2020 16:34:22
User entered 'No (N)'	System	17 Nov 2020 16:34:22

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-17T11:34:13', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5f7f7e36-9bb7-4da0-9186-c7d728290102'	(b) (4), (b) (6) System	17 Nov 2020 16:34:22
User entered 'No (N)'	System	17 Nov 2020 16:34:22

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-17T11:34:18', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '5f7f7e36-9bb7-4da0-9186-c7d728290102'	(b) (4), (b) (6) System	17 Nov 2020 16:34:22
User entered '17 Nov 2020 11:34:18'	System	17 Nov 2020 16:34:22

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
	System	06 Aug 2020 21:29:37
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 21:29:37

US3242013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:29
Data entry locked.	(b) (4), (b) (6)	
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 21:29:37
	System	06 Aug 2020 21:29:37

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2020-11-23T14:41:46', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '4f64e748-c6df-4a98-81c6-8997f2e07d0d'	System	23 Nov 2020 19:42:06
User entered 'No (N)'	System	23 Nov 2020 19:42:06

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2020-11-23T14:41:53', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '4f64e748-c6df-4a98-81c6-8997f2e07d0d'	System	23 Nov 2020 19:42:06
User entered 'No (N)'	System	23 Nov 2020 19:42:06

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-23T14:41:59', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '4f64e748-c6df-4a98-81c6-8997f2e07d0d'	System	23 Nov 2020 19:42:06
User entered '23 Nov 2020 14:41:59'	System	23 Nov 2020 19:42:06

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2020-11-30T09:05:45', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'b5b76146-43d0-4674-84f0-09fd2d942c5f'	System	30 Nov 2020 14:05:56
User entered 'No (N)'	System	30 Nov 2020 14:05:56

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2020-11-30T09:05:50', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'b5b76146-43d0-4674-84f0-09fd2d942c5f'	System	30 Nov 2020 14:05:56
User entered 'No (N)'	System	30 Nov 2020 14:05:56

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-11-30T09:05:53', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'b5b76146-43d0-4674-84f0-09fd2d942c5f'	System	30 Nov 2020 14:05:56
User entered '30 Nov 2020 09:05:53'	System	30 Nov 2020 14:05:56

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2020-12-05T00:07:01', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7331cd14-3697-4278-b96b-006f49c9d52b'	System	05 Dec 2020 05:07:16
User entered 'No (N)'	System	05 Dec 2020 05:07:16

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2020-12-05T00:07:10', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7331cd14-3697-4278-b96b-006f49c9d52b'	System	05 Dec 2020 05:07:16
User entered 'No (N)'	System	05 Dec 2020 05:07:16

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-12-05T00:07:12', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7331cd14-3697-4278-b96b-006f49c9d52b'	System	05 Dec 2020 05:07:16
User entered '05 Dec 2020 00:07:12'	System	05 Dec 2020 05:07:16

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2020-12-12T10:42:58', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e20acc9d-e8e4-4ec7-93bf-5224cbbcee76'	System	12 Dec 2020 15:43:07
User entered 'No (N)'	System	12 Dec 2020 15:43:07

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2020-12-12T10:43:04', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e20acc9d-e8e4-4ec7-93bf-5224cbbcee76'	System	12 Dec 2020 15:43:07
User entered 'No (N)'	System	12 Dec 2020 15:43:07

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-12-12T10:43:06', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e20acc9d-e8e4-4ec7-93bf-5224cbbcee76'	System	12 Dec 2020 15:43:07
User entered '12 Dec 2020 10:43:06'	System	12 Dec 2020 15:43:07

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2020-12-19T07:20:10', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '0696a219-664f-42c1-a7ea-8b23370d691c'	System	19 Dec 2020 12:20:20
User entered 'No (N)'	System	19 Dec 2020 12:20:20

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2020-12-19T07:20:14', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '0696a219-664f-42c1-a7ea-8b23370d691c'	System	19 Dec 2020 12:20:20
User entered 'No (N)'	System	19 Dec 2020 12:20:20

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-12-19T07:20:16', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '0696a219-664f-42c1-a7ea-8b23370d691c'	System	19 Dec 2020 12:20:20
User entered '19 Dec 2020 07:20:16'	System	19 Dec 2020 12:20:20

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2020-12-28T08:31:34', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7502095c-81c9-4b1c-aaf7-a7dbcc7a79f0'	System	28 Dec 2020 13:31:43
User entered 'No (N)'	System	28 Dec 2020 13:31:43

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2020-12-28T08:31:38', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7502095c-81c9-4b1c-aaf7-a7dbcc7a79f0'	System	28 Dec 2020 13:31:43
User entered 'No (N)'	System	28 Dec 2020 13:31:43

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2020-12-28T08:31:41', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7502095c-81c9-4b1c-aaf7-a7dbcc7a79f0'	System	28 Dec 2020 13:31:43
User entered '28 Dec 2020 08:31:41'	System	28 Dec 2020 13:31:43

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2021-01-04T13:59:09', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '574a7224-38d7-46d1-ace1-7d36a786e71f'	System	04 Jan 2021 18:59:20
User entered 'No (N)'	System	04 Jan 2021 18:59:20

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-01-04T13:59:12', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '574a7224-38d7-46d1-ace1-7d36a786e71f'	System	04 Jan 2021 18:59:20
User entered 'No (N)'	System	04 Jan 2021 18:59:20

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-01-04T13:59:15', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '574a7224-38d7-46d1-ace1-7d36a786e71f' User entered '04 Jan 2021 13:59:15'	System	04 Jan 2021 18:59:20
	System	04 Jan 2021 18:59:20

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2021-01-11T16:49:28', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8fb15f22-00c9-4de1-a2d9-513d0c28a7a7'	System	11 Jan 2021 21:49:51
User entered 'No (N)'	System	11 Jan 2021 21:49:51

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-01-11T16:49:38', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8fb15f22-00c9-4de1-a2d9-513d0c28a7a7'	System	11 Jan 2021 21:49:51
User entered 'No (N)'	System	11 Jan 2021 21:49:51

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-01-11T16:49:45', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8fb15f22-00c9-4de1-a2d9-513d0c28a7a7'	System	11 Jan 2021 21:49:51
User entered '11 Jan 2021 16:49:45'	System	11 Jan 2021 21:49:51

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2021-01-18T10:24:54', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '34fc7e2a-94d1-4e05-82c3-2bc9bf5481a0'	System	18 Jan 2021 15:25:09
User entered 'No (N)'	System	18 Jan 2021 15:25:09

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-01-18T10:25:03', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '34fc7e2a-94d1-4e05-82c3-2bc9bf5481a0'	System	18 Jan 2021 15:25:09
User entered 'No (N)'	System	18 Jan 2021 15:25:09

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-01-18T10:25:06', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '34fc7e2a-94d1-4e05-82c3-2bc9bf5481a0'	System	18 Jan 2021 15:25:09
User entered '18 Jan 2021 10:25:06'	System	18 Jan 2021 15:25:09

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2021-01-23T08:39:32', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2fd9624-91d0-4522-83d6-c458a25e620a'	System	23 Jan 2021 13:39:41
User entered 'No (N)'	System	23 Jan 2021 13:39:41

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-01-23T08:39:35', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2fd9624-91d0-4522-83d6-c458a25e620a'	System	23 Jan 2021 13:39:41
User entered 'No (N)'	System	23 Jan 2021 13:39:41

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-01-23T08:39:37', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2fd9624-91d0-4522-83d6-c458a25e620a'	System	23 Jan 2021 13:39:41
User entered '23 Jan 2021 08:39:37'	System	23 Jan 2021 13:39:41

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-02-01T14:10:21', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7ac0b1e8-f542-4c6e-af0a-ec7db73d39af'	System	01 Feb 2021 19:10:30
User entered 'No (N)'	System	01 Feb 2021 19:10:30

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-02-01T14:10:25', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7ac0b1e8-f542-4c6e-af0a-ec7db73d39af'	System	01 Feb 2021 19:10:30
User entered 'No (N)'	System	01 Feb 2021 19:10:30

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-02-01T14:10:28', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '7ac0b1e8-f542-4c6e-af0a-ec7db73d39af'	System	01 Feb 2021 19:10:30
User entered '01 Feb 2021 14:10:28'	System	01 Feb 2021 19:10:30

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-02-06T09:36:44', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '48ca5c4c-fb03-4ebb-8935-f3d570a860d9'	System	06 Feb 2021 14:36:52
User entered 'No (N)'	System	06 Feb 2021 14:36:52

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-02-06T09:36:47', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '48ca5c4c-fb03-4ebb-8935-f3d570a860d9'	System	06 Feb 2021 14:36:52
User entered 'No (N)'	System	06 Feb 2021 14:36:52

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-02-06T09:36:49', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '48ca5c4c-fb03-4ebb-8935-f3d570a860d9'	System	06 Feb 2021 14:36:52
User entered '06 Feb 2021 09:36:49'	System	06 Feb 2021 14:36:52

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2021-02-13T11:16:34', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '97a2fd4e-e4be-4d10-8492-0f4c2cbce632'	System	13 Feb 2021 16:16:50
User entered 'No (N)'	System	13 Feb 2021 16:16:50

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-02-13T11:16:39', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '97a2fd4e-e4be-4d10-8492-0f4c2cbce632'	System	13 Feb 2021 16:16:50
User entered 'No (N)'	System	13 Feb 2021 16:16:50

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-02-13T11:16:48', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '97a2fd4e-e4be-4d10-8492-0f4c2cbce632'	System	13 Feb 2021 16:16:50
User entered '13 Feb 2021 11:16:48'	System	13 Feb 2021 16:16:50

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[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 (71131727eadd8a2c)', Time: '2021-02-20T00:15:19', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ceaac43c-3518-4610-a014-b7f3fb3dd794'	System	20 Feb 2021 05:15:37
User entered 'No (N)'	System	20 Feb 2021 05:15:37

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-02-20T00:15:26', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ceaac43c-3518-4610-a014-b7f3fb3dd794'	System	20 Feb 2021 05:15:37
User entered 'No (N)'	System	20 Feb 2021 05:15:37

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-02-20T00:15:29', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'ceaac43c-3518-4610-a014-b7f3fb3dd794'	System	20 Feb 2021 05:15:37
User entered '20 Feb 2021 00:15:29'	System	20 Feb 2021 05:15:37

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-02-27T11:12:45-05:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8a845410-80b3-43bb-8bb7-088e5fd0bcc8'	System	27 Feb 2021 16:12:59
User entered 'No (N)'	System	27 Feb 2021 16:12:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-02-27T11:12:51-05:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8a845410-80b3-43bb-8bb7-088e5fd0bcc8'	System	27 Feb 2021 16:12:59
User entered 'No (N)'	System	27 Feb 2021 16:12:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-02-27T11:12:54-05:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '8a845410-80b3-43bb-8bb7-088e5fd0bcc8'	System	27 Feb 2021 16:12:59
User entered '27 Feb 2021 11:12:54'	System	27 Feb 2021 16:12:59

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-03-06T07:32:51-05:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'aa0ae3-e414-454f-91b9-d73d40163083'	System	06 Mar 2021 12:33:00
User entered 'No (N)'	System	06 Mar 2021 12:33:00

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-03-06T07:32:54-05:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'aa0ae3-e414-454f-91b9-d73d40163083'	System	06 Mar 2021 12:33:00
User entered 'No (N)'	System	06 Mar 2021 12:33:00

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-03-06T07:32:57-05:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'aa0aeee3-e414-454f-91b9-d73d40163083' User entered '06 Mar 2021 07:32:57'	System	06 Mar 2021 12:33:00
	System	06 Mar 2021 12:33:00

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-03-14T22:08:43-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e8d5c08c-65d9-4bfa-b572-a4fb5aaf8f4a'	System	15 Mar 2021 02:08:55
User entered 'No (N)'	System	15 Mar 2021 02:08:55

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-03-14T22:08:47-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e8d5c08c-65d9-4bfa-b572-a4fb5aaf8f4a'	System	15 Mar 2021 02:08:55
User entered 'No (N)'	System	15 Mar 2021 02:08:55

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-03-14T22:08:50-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'e8d5c08c-65d9-4bfa-b572-a4fb5aaf8f4a'	System	15 Mar 2021 02:08:55
User entered '14 Mar 2021 22:08:50'	System	15 Mar 2021 02:08:55

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-03-22T10:56:05-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '12a4cf7e-5c80-4973-8b6d-6baac591b486'	System	22 Mar 2021 14:58:00
User entered 'No (N)'	System	22 Mar 2021 14:58:00

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-03-22T10:56:09-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '12a4cf7e-5c80-4973-8b6d-6baac591b486'	System	22 Mar 2021 14:58:00
User entered 'No (N)'	System	22 Mar 2021 14:58:00

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-03-22T10:57:55-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '12a4cf7e-5c80-4973-8b6d-6baac591b486' User entered '22 Mar 2021 10:57:55'	System	22 Mar 2021 14:58:00

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-03-30T13:59:35-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '69584933-28c8-4789-a60a-c2ef47ec9ef5'	System	30 Mar 2021 18:01:50
User entered 'No (N)'	System	30 Mar 2021 18:01:50

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-03-30T13:59:38-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '69584933-28c8-4789-a60a-c2ef47ec9ef5'	System	30 Mar 2021 18:01:50
User entered 'No (N)'	System	30 Mar 2021 18:01:50

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-03-30T14:01:48-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '69584933-28c8-4789-a60a-c2ef47ec9ef5'	System	30 Mar 2021 18:01:50
User entered '30 Mar 2021 14:01:48'	System	30 Mar 2021 18:01:50

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-04-05T11:50:38-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2f54707-49b6-4691-949e-9d15f724ac4a'	System	05 Apr 2021 15:50:56
User entered 'No (N)'	System	05 Apr 2021 15:50:56

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-04-05T11:50:48-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2f54707-49b6-4691-949e-9d15f724ac4a'	System	05 Apr 2021 15:50:56
User entered 'No (N)'	System	05 Apr 2021 15:50:56

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-04-05T11:50:50-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'c2f54707-49b6-4691-949e-9d15f724ac4a'	System	05 Apr 2021 15:50:56
User entered '05 Apr 2021 11:50:50'	System	05 Apr 2021 15:50:56

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-04-12T16:54:57-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'db72e116-5422-401d-8ffb-ce49b31439e3'	System	12 Apr 2021 20:55:08
User entered 'No (N)'	System	12 Apr 2021 20:55:08

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-04-12T16:55:01-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'db72e116-5422-401d-8ffb-ce49b31439e3'	System	12 Apr 2021 20:55:08
User entered 'No (N)'	System	12 Apr 2021 20:55:08

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-04-12T16:55:03-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'db72e116-5422-401d-8ffb-ce49b31439e3'	System	12 Apr 2021 20:55:08
User entered '12 Apr 2021 16:55:03'	System	12 Apr 2021 20:55:08

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-04-17T10:03:55-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '6ade8e4c-dd6a-43e0-b8de-87ce4c603673'	System	17 Apr 2021 14:04:02
User entered 'No (N)'	System	17 Apr 2021 14:04:02

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-04-17T10:03:58-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '6ade8e4c-dd6a-43e0-b8de-87ce4c603673'	System	17 Apr 2021 14:04:02
User entered 'No (N)'	System	17 Apr 2021 14:04:02

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-04-17T10:04:00-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '6ade8e4c-dd6a-43e0-b8de-87ce4c603673'	System	17 Apr 2021 14:04:02
User entered '17 Apr 2021 10:04:00'	System	17 Apr 2021 14:04:02

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

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 (71131727eadd8a2c)', Time: '2021-04-27T08:25:09-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a971a75a-048b-4777-b6d7-e7e751ffff01'	System	28 Apr 2021 23:56:48
User entered 'No (N)'	System	28 Apr 2021 23:56:48

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

Have you been exposed to someone with 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 (71131727eadd8a2c)', Time: '2021-04-27T08:25:12-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a971a75a-048b-4777-b6d7-e7e751ffff01'	System	28 Apr 2021 23:56:48
User entered 'No (N)'	System	28 Apr 2021 23:56:48

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-04-27T08:25:16-04:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: 'a971a75a-048b-4777-b6d7-e7e751ffff01'	System	28 Apr 2021 23:56:48
User entered '27 Apr 2021 08:25:16'	System	28 Apr 2021 23:56:48

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:09:04

US3242013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:09:04
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:09:04

US3242013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:10:07

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 11:13:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-02-27T11:13:04-05:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '65912caa-fdf5-4927-a18f-6bce1ef1eb66'	System	27 Feb 2021 16:13:11
User entered 'No (N)'	System	27 Feb 2021 16:13:11

US3242013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:10:07

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:13:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71131727eadd8a2c)', Time: '2021-02-27T11:13:07-05:00', User OID: 'PatientReportedOutcome (US3242013)', ODM File OID: '65912caa-fdf5-4927-a18f-6bce1ef1eb66'	System	27 Feb 2021 16:13:11
User entered '27 Feb 2021 11:13:07'	System	27 Feb 2021 16:13:11

US3242013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Nov 2020 20:24:56
	(b) (4)	

US3242013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	19 Nov 2020 20:24:56
	(b) (4)	

US3242013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	19 Nov 2020 20:24:56
	(b) (4)	

US3242013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	19 Nov 2020 20:24:56
	(b) (4)	

US3242013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Nov 2020 20:25:00
	(b) (4)	

US3242013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:09
User entered 'I'	(b) (4), (b) (6) System	19 Nov 2020 20:25:00

US3242013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	30 Nov 2020 22:14:26

US3242013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '30 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	30 Nov 2020 22:14:26

US3242013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	30 Nov 2020 22:14:26
	(b) (4)	

US3242013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Nov 2020 22:14:26
	(b) (4)	

US3242013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Nov 2020 22:14:29
	(b) (4)	

US3242013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered 'I'	(b) (4), (b) (6) System	30 Nov 2020 22:14:29

US3242013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Dec 2020 21:44:19
	(b) (4)	

US3242013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '30 Dec 2020'	Erynn McKinley (b) (4)	30 Dec 2020 21:44:19
	(b) (4)	

US3242013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	30 Dec 2020 21:44:19
	(b) (4)	

US3242013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Dec 2020 21:44:19
	(b) (4)	

US3242013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Dec 2020 21:44:22
	(b) (4)	

US3242013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered 'I'	(b) (4), (b) (6) System	30 Dec 2020 21:44:22

US3242013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Feb 2021 20:11:49
	(b) (4)	

US3242013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '29 Jan 2021'	Erynn McKinley (b) (4)	02 Feb 2021 20:11:49
	(b) (4)	

US3242013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	02 Feb 2021 20:11:49
	(b) (4)	

US3242013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	02 Feb 2021 20:11:49
	(b) (4)	

US3242013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Feb 2021 20:11:53
	(b) (4)	

US3242013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered '1'	(b) (4), (b) (6) System	02 Feb 2021 20:11:53

US3242013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:55:05
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	11 Mar 2021 22:29:48
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:55:05
	(b) (4)	
User entered '11 Mar 2021'	Erynn McKinley (b) (4)	11 Mar 2021 22:29:48
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[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 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:55:05
	(b) (4)	
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	11 Mar 2021 22:29:48
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered 'VISIT4'	(b) (4), (b) (6) System	11 Mar 2021 22:29:48

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	01 Apr 2021 19:38:21
	(b) (4)	
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 16:09:36
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	01 Apr 2021 19:38:21
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 16:09:36
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	01 Apr 2021 19:38:21
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 16:09:36
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:09:36

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:38:21
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 16:09:36

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:38:21
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 16:09:36

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	01 Apr 2021 19:38:21
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 16:09:36
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	01 Apr 2021 19:38:21
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 16:09:36
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:09:36

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	01 Apr 2021 19:38:21
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 16:09:36
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:09:36

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:38:21
User entered empty.	Erynn McKinley (b) (4) (b) (4)	30 Mar 2021 16:09:36

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:09:36

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	01 Apr 2021 19:38:21
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 16:09:36
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:09:36

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:58:20

US3242013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 14:58:20

US3242013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:55:05
	(b) (4)	
User entered 'No (N)'	Erynn McKinley (b) (4)	11 Mar 2021 22:29:57
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:55:05
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	11 Mar 2021 22:29:57
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:55:05
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	15 Mar 2021 14:38:06
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Mar 2021 14:38:19
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		15 Mar 2021 14:38:19
User entered '11 Mar 2021' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	15 Mar 2021 14:38:19
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Mar 2021 14:38:06
User entered '15 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	15 Mar 2021 14:38:06

US3242013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:55:05
	(b) (4)	
User entered '15:50'	Erynn McKinley (b) (4)	15 Mar 2021 14:38:06
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered '11 Mar 2021 15:50'	(b) (4), (b) (6)	
	System	15 Mar 2021 14:38:19
User entered '15 Mar 2021 15:50'	System	15 Mar 2021 14:38:06

US3242013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:55:05
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	11 Mar 2021 22:30:12
	(b) (4)	

US3242013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:58:20
User entered 'I'	(b) (4), (b) (6) System	11 Mar 2021 22:30:12

US3242013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:38:21
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	31 Mar 2021 20:16:37

US3242013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:38:21
User entered '30 Mar 2021' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	31 Mar 2021 20:18:13
User entered '31 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	31 Mar 2021 20:16:37

US3242013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:38:21
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	31 Mar 2021 20:16:37

US3242013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:38:21
User entered empty.	Erynn McKinley (b) (4) (b) (4)	31 Mar 2021 20:16:37

US3242013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	01 Apr 2021 19:38:21
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	31 Mar 2021 20:16:40

US3242013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:04
User entered 'I'	System	31 Mar 2021 20:16:40

US3242013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	29 Apr 2021 13:49:42
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	28 Apr 2021 22:48:47

US3242013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	29 Apr 2021 13:49:42
	(b) (4)	
User entered '28 Apr 2021'	Donna Toepfer (b) (4)	28 Apr 2021 22:48:47
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	29 Apr 2021 13:49:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	28 Apr 2021 22:48:47
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	29 Apr 2021 13:49:42
User entered empty.	(b) (4) Donna Toepfer (b) (4)	28 Apr 2021 22:48:47

US3242013

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 21:25:36

US3242013

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 21:25:36

US3242013

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

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:03

US3242013

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

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:03

US3242013

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

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:03

US3242013

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

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 21:47:03

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:29

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[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 10:36:57
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:12:21

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:29

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:12:21

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:29

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Placebo (Placebo)'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:29

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Placebo (Placebo)'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:29

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Placebo (Placebo)'	Donna Toepfer (b) (4) (b) (4) (b) (4)	26 Jan 2021 21:47:29

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:47:29

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '1'	(b) (4), (b) (6) System	26 Jan 2021 21:47:29

US3242013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:07

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '1'	(b) (4), (b) (6) System	26 Jan 2021 21:47:29

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 21:48:31
DataPoint set to visible.	System	26 Jan 2021 21:47:29

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 21:48:31
DataPoint set to visible.	System	26 Jan 2021 21:47:29

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '15:56'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '26 Jan 2021 15:56'	(b) (4), (b) (6) System	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '97.5' F	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '80'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'bpm'	(b) (4), (b) (6) System	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '16'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'breaths/min'	(b) (4), (b) (6) System	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '116'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'mmHg'	(b) (4), (b) (6) System	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '70'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'mmHg'	(b) (4), (b) (6) System	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	26 Jan 2021 21:48:31

US3242013

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 21:48:31
DataPoint set to visible.	System	26 Jan 2021 21:47:29

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '17:07'	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '26 Jan 2021 17:07'	(b) (4), (b) (6) System	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '97.8' F	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '72'	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'bpm'	(b) (4), (b) (6) System	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '14'	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'breaths/min'	(b) (4), (b) (6) System	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '114'	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'mmHg'	(b) (4), (b) (6) System	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '70'	Donna Toepfer (b) (4)	26 Jan 2021 22:30:59

US3242013

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'mmHg'	(b) (4), (b) (6) System	26 Jan 2021 22:30:59

US3242013

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'No (N)'	Donna Toepfer (b) (4)	26 Jan 2021 21:48:46

US3242013

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	26 Jan 2021 21:48:46

US3242013

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:08

US3242013

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:08

US3242013

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Urine (URINE)'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:08

US3242013

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Negative (NEGATIVE)'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:08

US3242013

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	26 Jan 2021 21:49:08

US3242013

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	26 Jan 2021 21:49:08

US3242013

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	26 Jan 2021 21:49:08

US3242013

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered empty.	(b) (4), (b) (6) System	26 Jan 2021 21:49:08

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:28

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	26 Jan 2021 21:49:28

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

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 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered empty.	Donna Toepfer (b) (4)	26 Jan 2021 21:49:28

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'mRNA-1273'	(b) (4), (b) (6)	26 Jan 2021 21:49:28
DataPoint set to visible.	System	26 Jan 2021 21:47:29

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:28

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '16:35'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:28

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '26 Jan 2021 16:35'	(b) (4), (b) (6) System	26 Jan 2021 21:49:28

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:28

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'ONCE'	(b) (4), (b) (6) System	26 Jan 2021 21:49:28

US3242013

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

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	26 Jan 2021 21:49:28

US3242013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:47

US3242013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:47

US3242013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered '15:39'	Donna Toepfer (b) (4)	26 Jan 2021 21:49:47

US3242013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '26 Jan 2021 15:39'	(b) (4), (b) (6) System	26 Jan 2021 21:49:47

US3242013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:15
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:50:16

US3242013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:15
User entered '26 Jan 2021'	Donna Toepfer (b) (4)	26 Jan 2021 21:50:16

US3242013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:15
User entered '15:32'	Donna Toepfer (b) (4)	26 Jan 2021 21:50:16

US3242013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:07

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '26 Jan 2021 15:32'	(b) (4), (b) (6) System	26 Jan 2021 21:50:16

US3242013

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

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:15
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	26 Jan 2021 21:50:22

US3242013

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

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:36:57
User entered '1'	(b) (4), (b) (6) System	26 Jan 2021 21:50:22

US3242013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:44
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	02 Feb 2021 15:37:18

US3242013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered '2 Feb 2021'	Erynn McKinley (b) (4)	02 Feb 2021 15:37:18
	(b) (4)	

US3242013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	02 Feb 2021 15:37:18
	(b) (4)	

US3242013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	02 Feb 2021 15:37:18
	(b) (4)	

US3242013

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:04:44
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Feb 2021 15:39:06
	(b) (4)	

US3242013

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User entered '1'	(b) (4), (b) (6) System	02 Feb 2021 15:39:06

US3242013

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User entered '1'	(b) (4), (b) (6)	02 Feb 2021 15:39:06
DataPoint set to visible.	System	02 Feb 2021 15:39:06

US3242013

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:42:55

US3242013

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 09:47:32
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'value is correct' (Site from System).	Donna Toepfer (b) (4)	11 Mar 2021 23:38:04
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Mar 2021 22:42:55
User entered '11 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:42:55

US3242013

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:42:55

US3242013

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered 'OLD29'	System	11 Mar 2021 22:42:55

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User accepted default value 'Post-Dose (POSTDOSE)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:19
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:43:53

US3242013

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:03

US3242013

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:03

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:30

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered '11 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:30

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Urine (URINE)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:30

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:58
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 11:46:39
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'form was submitted' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 20:27:57
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	19 Apr 2021 20:27:41
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 20:27:41
User entered 'Positive (POSITIVE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:27:41
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Negative (NEGATIVE)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:30

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:58
User closed query 'Per CDM: Please verify Was pregnancy test performed? is recorded as Yes; However Was FSH sample collected? Is recorded as "NO". Please review and update accordingly, Else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:44:57
Query 'Per CDM: Please verify Was pregnancy test performed? is recorded as Yes; However Was FSH sample collected? Is recorded as "NO". Please review and update accordingly, Else clarify.' answered with 'confirm, fsh not collected' (Site from DM).	Donna Toepfer (b) (4)	22 Mar 2021 13:27:29
User opened query 'Per CDM: Please verify Was pregnancy test performed? is recorded as Yes; However Was FSH sample collected? Is recorded as "NO". Please review and update accordingly, Else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 15:56:10
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:30

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:30

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:30

US3242013

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:10:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:44:30

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		11 Mar 2021 23:33:24
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	11 Mar 2021 23:33:24
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	11 Mar 2021 22:44:54
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:44:54
DataPoint set to visible.	System	02 Feb 2021 15:39:06

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:20:53
User entered empty.	System	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered empty.	System	11 Mar 2021 22:44:54

US3242013

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:21:29
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	11 Mar 2021 22:45:05

US3242013

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:05:33
User entered '1'	System	11 Mar 2021 22:45:05

US3242013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	25 Mar 2021 18:09:14
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	22 Mar 2021 15:14:29

US3242013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	25 Mar 2021 18:09:14
	(b) (4)	
User entered '22 Mar 2021'	Erynn McKinley (b) (4)	22 Mar 2021 15:14:29
	(b) (4)	

US3242013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	25 Mar 2021 18:09:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	22 Mar 2021 15:14:29
	(b) (4)	

US3242013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	25 Mar 2021 18:09:14
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	22 Mar 2021 15:14:29
	(b) (4)	

US3242013

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	25 Mar 2021 18:09:14
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	22 Mar 2021 15:14:34
	(b) (4)	

US3242013

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:17:05
User entered 'I'	(b) (4), (b) (6) System	22 Mar 2021 15:14:34

US3242013

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 21:30:40
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 21:30:40

US3242013

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 21:30:40

US3242013

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	19 Apr 2021 21:30:40

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:10:07**

[Visit Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '19 Apr 2021'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:35:25
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:10:07**

[Physical Exam](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '0'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:35:25
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:10:07**

[Vital Signs](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '1'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:35:25
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:10:07**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '0' reason for change: Data Entry Error	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:44:10
User entered '1'	Donna Toepfer (b) (4)	19 Apr 2021 21:35:25

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:10:07**

[Pregnancy Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered 'I'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:35:25
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered 'Yes (Y)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:05

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '19 Apr 2021'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

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

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '16:14'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

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

Audit	User	Time (GMT)
User entered '19 Apr 2021 16:14'	System	19 Apr 2021 21:36:05

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '97.1' F	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered 'Oral (Oral)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
	(b) (4)	
User entered '80'	Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	(b) (4)	
	(b) (4)	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 21:36:05

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

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

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '16'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 21:36:05

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

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

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
	(b) (4)	
User entered '118'	Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 21:36:05

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

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

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '70'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:05
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:10:07**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 21:36:05

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Generated On: **09 Jun 2021 16:10:07**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered 'Yes (Y)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:21

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Generated On: **09 Jun 2021 16:10:07**

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '19 Apr 2021'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:21
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Generated On: **09 Jun 2021 16:10:07**

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered 'Urine (URINE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:21
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Generated On: **09 Jun 2021 16:10:07**

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered 'Negative (NEGATIVE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 21:36:21
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Generated On: **09 Jun 2021 16:10:07**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 21:36:21
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Generated On: **09 Jun 2021 16:10:07**

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 21:36:21
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Generated On: **09 Jun 2021 16:10:07**

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 21:36:21
	[REDACTED]	
	[REDACTED]	

US3242013

Folder: **Unscheduled 19 Apr 2021**

Form: **Pregnancy Test**

Generated On: **09 Jun 2021 16:10:07**

Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:36:21

US3242013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:10:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:07
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
Signature has been broken.	Donna Toepfer (b) (4)	06 Apr 2021 20:09:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	06 Apr 2021 20:09:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:15
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	04 Feb 2021 19:59:51

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:39:28
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
User entered 'USA-US067-2021-mRNA-1273-P301000013'	System	07 Apr 2021 17:06:37
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 17:06:37

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLG: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Spontaneous abortion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:14:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:14:41
Data point term sent to Coder	System	06 Apr 2021 20:11:52
User entered 'Spontaneous Abortion'	Donna Toepfer (b) (4) (b) (4) (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
User entered '17 Mar 2021'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '17 Mar 2021'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
User entered empty.	(b) (4) Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '1'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		06 Apr 2021 20:12:14
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		06 Apr 2021 20:12:14
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	06 Apr 2021 20:11:27
User entered '0'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
User entered empty.	(b) (4) Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
User entered empty.	(b) (4) Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	06 Apr 2021 20:12:14
User entered 'No (N)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 14:34:25
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 14:09:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User closed query 'PV Query: Please clarify action taken listed as withdrawn. EDC reports last dose on 26 Jan 2021, but answered query reports that the subject has had all vaccinations. Please clarify. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:43:35
Query 'PV Query: Please clarify action taken listed as withdrawn. EDC reports last dose on 26 Jan 2021, but answered query reports that the subject has had all vaccinations. Please clarify. ' answered with 'subject did not receive last vaccine' (Site from Safety).	Donna Toepfer (b) (4)	19 Apr 2021 15:19:58
User opened query 'PV Query: Please clarify action taken listed as withdrawn. EDC reports last dose on 26 Jan 2021, but answered query reports that the subject has had all vaccinations. Please clarify. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:43:28
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'PV Query: As pregnancy form indicates study drug was withdrawn, please consider updating action taken in EDC to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:39:21
Signature has been broken.	Donna Toepfer (b) (4)	09 Apr 2021 17:17:17
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Apr 2021 17:17:17
Query 'PV Query: As pregnancy form indicates study drug was withdrawn, please consider updating action taken in EDC to withdrawn.' answered with 'subject has completed all vaccinations. ' (Site from Safety).	Donna Toepfer (b) (4)	09 Apr 2021 17:07:17

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: As pregnancy form indicates study drug was withdrawn, please consider updating action taken in EDC to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:08:22
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
User entered 'Not Applicable (NOT APPLICABLE)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '1'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
User entered '0'	(b) (4) Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
User entered empty.	(b) (4) Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:24
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:39:25
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:39:24
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'meds add, no surgical procedures' (Site from Safety).	Donna Toepfer (b) (4)	10 Apr 2021 13:36:39
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'confirm sent' (Site from Safety).	Donna Toepfer (b) (4)	10 Apr 2021 13:36:03
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:08:55

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:08:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
User entered 'Subject experienced a miscarriage on 3/17/2021. Subject went to ER due to extremely heavy bleeding and was informed of a miscarriage. No other problems and doing well.'	Donna Toepfer (b) (4)	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:11:27

US3242013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 20:11:27

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:55
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
Signature has been broken.	Donna Toepfer (b) (4)	11 Mar 2021 23:33:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	11 Mar 2021 23:33:55
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:04:15
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	04 Feb 2021 20:00:51

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 02:07:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 02:07:54
Data point term sent to Coder	System	11 Mar 2021 23:35:37
User entered 'Prenatal Multivitamin'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	25 Mar 2021 18:09:14
User closed query 'Per DM CLR: Indication=Prophylaxis. Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update this field to 'No' as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:06:56
Query 'Per DM CLR: Indication=Prophylaxis. Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update this field to 'No' as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	22 Mar 2021 13:26:35
Signature has been broken.	Donna Toepfer (b) (4)	22 Mar 2021 13:26:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Mar 2021 13:26:21
User opened query 'Per DM CLR: Indication=Prophylaxis. Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update this field to 'No' as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 10:59:55
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Supplement for Pregnancy'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered '1'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'tablet (TABLET)'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'once daily (QD)'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered '22 Feb 2021'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered '0'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered empty.	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 15:55:05
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Mar 2021 23:35:13

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 07:59:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 07:59:54
Data point term sent to Coder	System	10 Apr 2021 13:38:32
User entered 'KETOROLAC' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:38:25
User entered 'Detorolac'	Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'Spontaneous abortion'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '30'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'mg (mg)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered empty.	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'once (ONCE)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered empty.	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered empty.	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '17 Mar 2021'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '0'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '17 Mar 2021'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User entered empty.	System	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User entered empty.	System	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:29
User entered empty.	System	10 Apr 2021 13:38:05

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: UTEROTONICS, ATC: PROSTAGLANDINS, PRODUCT: MISOPROSTOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 08:44:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:44:07
Data point term sent to Coder	System	10 Apr 2021 13:39:32
User entered 'Misoprostol'	Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'Spontaneous abortion'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'tapering dose'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'ug (ug)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered empty.	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'as needed (PRN)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered empty.	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'Oral (ORAL)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered empty.	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '17 Mar 2021'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '0'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '17 Mar 2021'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User entered empty.	System	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User entered empty.	System	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:34
User entered empty.	System	10 Apr 2021 13:39:19

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:17:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:17:49
User signature succeeded.	Jon Finley (b) (4) (b) (4)	13 Apr 2021 13:01:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:01:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:01:48
Data point term sent to Coder	System	10 Apr 2021 13:42:33
Data point term sent to Coder	System	10 Apr 2021 13:41:33
User entered 'Sodium Chloride'	Donna Toepfer (b) (4) (b) (4) (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Apr 2021 13:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Apr 2021 13:41:41
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Apr 2021 13:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Apr 2021 13:41:41
User entered 'Spontaneous abortion' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Apr 2021 13:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Apr 2021 13:41:41
User entered '0.9' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Apr 2021 13:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Apr 2021 13:41:41
User entered 'Other (OTHER)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '%' reason for change: Data Entry Error	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Apr 2021 13:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Apr 2021 13:41:41
User entered 'as needed (PRN)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered empty.	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Apr 2021 13:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Apr 2021 13:41:41
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered empty.	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4) (b) (4)	13 Apr 2021 13:01:18
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	10 Apr 2021 13:41:41
User entered '17 Mar 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '0'	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Apr 2021 13:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Apr 2021 13:41:41
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '17 Mar 2021' reason for change: Data Entry Error	(b) (4) Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Apr 2021 13:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Apr 2021 13:41:41
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Apr 2021 13:40:46
User entered empty.	Donna Toepfer (b) (4)	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User entered empty.	System	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User entered empty.	System	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:56:38
User entered empty.	System	10 Apr 2021 13:40:46

US3242013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:10:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:53:51
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	31 Aug 2020 13:46:03
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 16:11:43

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'USA-US067-2021-MRNA-1273-P301000013'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Yes (Y)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Yes (Y)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'Jon'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Nathan'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'Finley'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Segall'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered '175 Country Club Drive'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered '175 country club dr st100a'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Stockbridge'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'GA'	System	20 Apr 2021 19:47:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:47:40
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
Un-reviewed for Safety.	(b) (4)	12 Apr 2021 14:39:49
Signature has been broken.	System	12 Apr 2021 14:39:49
User entered empty.	System	12 Apr 2021 14:39:49
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:39:38
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:43:45

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	03 May 2021 14:11:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 13:59:42
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 May 2021 13:58:31
Signature has been broken.	Donna Toepfer (b) (4)	03 May 2021 13:58:31
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 May 2021 13:58:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered (b) (4)	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered '30281'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'US'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 19:47:56
User entered '2'	System	12 Apr 2021 14:39:49
User entered '1'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'USA-US067-2021-MRNA-1273-P301000013'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Yes (Y)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Yes (Y)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'Jon'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Nathan'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'Finley'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Segall'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered '175 Country Club Drive'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered '175 country club dr st100a'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Stockbridge'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'GA'	System	20 Apr 2021 19:47:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:47:40
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
Un-reviewed for Safety.	(b) (4)	12 Apr 2021 14:39:49
Signature has been broken.	System	12 Apr 2021 14:39:49
User entered empty.	System	12 Apr 2021 14:39:49
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:39:38
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:43:45

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	03 May 2021 14:11:31
DataPoint Verified.	(b) (4)	03 May 2021 13:59:42
DataPoint Un-verified.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	03 May 2021 13:58:31
Signature has been broken.	Donna Toepfer (b) (4)	03 May 2021 13:58:31
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 May 2021 13:58:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered (b) (4)	System	20 Apr 2021 19:47:56
User signature succeeded.	System	20 Apr 2021 19:47:56
	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered '30281'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'US'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 19:47:56
User entered '2'	System	12 Apr 2021 14:39:49
User entered '1'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:10:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered '07/Apr/2021 13:08'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:10:07

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)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'l'	(b) (4), (b) (6)	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'USA-US067-2021-MRNA-1273-P301000013'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Yes (Y)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Yes (Y)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'Jon'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Nathan'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'Finley'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Segall'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered '175 Country Club Drive'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered '175 country club dr st100a'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Stockbridge'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'GA'	System	20 Apr 2021 19:47:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:47:40
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
Un-reviewed for Safety.	(b) (4)	12 Apr 2021 14:39:49
Signature has been broken.	System	12 Apr 2021 14:39:49
User entered empty.	System	12 Apr 2021 14:39:49
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:39:38
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:43:45

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	03 May 2021 14:11:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 13:59:42
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 May 2021 13:58:31
Signature has been broken.	Donna Toepfer (b) (4)	03 May 2021 13:58:31
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 May 2021 13:58:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered (b) (4)	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered '30281'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'US'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 19:47:56
User entered '2'	System	12 Apr 2021 14:39:49
User entered '1'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:10:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '12/Apr/2021 09:39'	(b) (4) System	12 Apr 2021 14:39:49

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:10:07

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)	22 Apr 2021 14:04:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:47:40
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:39:49

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'USA-US067-2021-MRNA-1273-P301000013'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Yes (Y)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Yes (Y)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'No (N)'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'Jon'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Nathan'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'Finley'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered 'Segall'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered '175 Country Club Drive'	System	20 Apr 2021 19:47:56
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered '175 country club dr st100a'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'Stockbridge'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 19:47:56
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered 'GA'	System	20 Apr 2021 19:47:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:47:40
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
Un-reviewed for Safety.	(b) (4)	12 Apr 2021 14:39:49
Signature has been broken.	System	12 Apr 2021 14:39:49
User entered empty.	System	12 Apr 2021 14:39:49
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:39:38
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:43:45

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	03 May 2021 14:11:31
DataPoint Verified.	(b) (4)	03 May 2021 13:59:42
DataPoint Un-verified.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	03 May 2021 13:58:31
Signature has been broken.	Donna Toepfer (b) (4)	03 May 2021 13:58:31
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 May 2021 13:58:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:31
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	20 Apr 2021 19:47:56
User entered (b) (4)	System	20 Apr 2021 19:47:56
User signature succeeded.	System	20 Apr 2021 19:47:56
	Nathan Segall (b) (4)	08 Apr 2021 20:53:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:08:29
User entered '30281'	System	07 Apr 2021 17:06:37

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:53:00
Reviewed for Safety.	(b) (4)	07 Apr 2021 17:08:29
User entered 'US'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 19:47:56
User entered '2'	System	12 Apr 2021 14:39:49
User entered '1'	System	07 Apr 2021 17:08:22

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:10:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '20/Apr/2021 15:47'	(b) (4) System	20 Apr 2021 19:47:56

US3242013

Folder: SAE USA-US067-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:10:07

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)	22 Apr 2021 14:04:00
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:17:31
User entered '1'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:47:56