

US3062118 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:02:24

All time stamps listed in this document are displayed in GMT

US3062118

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Participant ID

US3062118

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

US3062118

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 15:27:30

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Date of Informed Consent (*dd MMM yyyy*) 06 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:27:30

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 15:27:30

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 15:27:30

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	01 APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	01 JAN 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:27:30

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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>)	11:09 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 11:09
Height (<i>xxx.x</i>)	167.0 cm
Weight (<i>xxx.x</i>)	74 kg
BMI (<i>xxx.x</i>)	26.53376 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 15:27:30

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Date of assessment (*dd MMM yyyy*) 06 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*) 01 JAN 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:27:30

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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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:27:30

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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

What was the participant's randomization number? 184882

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) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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>)	11:09 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 11:09
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 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>)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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>)	13:11 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 13:11
Temperature (<i>xxx.x</i>)	96.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	57 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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) 12:39 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 12:39

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	06 AUG 2020
Collection time (<i>00:00-23:59</i>)	11:27 (24 HR)
Collection date and time (derived)	06 AUG 2020 11:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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	11:31	06 AUG 2020 11:31
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.1 °F

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

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

PC Time Stamp 06 AUG 2020 13:17

PC Open Date & Time 06 AUG 2020 12:59

PC Close Date & Time 06 AUG 2020 15:29

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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 97.8 °F

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

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

PC Time Stamp 07 AUG 2020 05:38
PC Open Date & Time 06 AUG 2020 16:24
PC Close Date & Time 07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

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	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 AUG 2020 04:33
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

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	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	09 AUG 2020 05:21
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °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	10 AUG 2020 05:20
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °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	11 AUG 2020 05:15
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

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

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

PC Time Stamp	12 AUG 2020 05:20
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 AUG 2020 05:54
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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 13:18

PC Open Date & Time

06 AUG 2020 12:59

PC Close Date & Time

06 AUG 2020 15:29

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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 05:39

PC Open Date & Time

06 AUG 2020 16:24

PC Close Date & Time

07 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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 04:34

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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 05:22

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

10 AUG 2020 05:20

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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 05:15

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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 05:20

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

13 AUG 2020 05:54

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

No

Yes

PC Time stamp	06 AUG 2020 13:18
PC Open Date & Time	06 AUG 2020 12:59
PC Close Date & Time	06 AUG 2020 15:29

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

No

Yes

PC Time stamp	07 AUG 2020 05:40
PC Open Date & Time	06 AUG 2020 16:24
PC Close Date & Time	07 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 04:35
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 05:22
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 05:21
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

Yes

PC Time stamp	11 AUG 2020 05:16
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 05:21
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

Yes

PC Time stamp	13 AUG 2020 05:55
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3062118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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>)	3 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:25 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 11:25
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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>)	13:04 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:04
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>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3062118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 12:26 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 12:26

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

US3062118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	3 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:53 (24 HR)
Collection date and time (derived)	3 SEP 2020 11:53

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Collection date (<i>dd MMM yyyy</i>)			3 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	11:56	3 SEP 2020 11:56
Nasopharyngeal Swab 2	No		

US3062118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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 97.9 °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 03 SEP 2020 13:08

PC Open Date & Time 03 SEP 2020 12:46

PC Close Date & Time 03 SEP 2020 15:16

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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** 98.6 °F

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

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

PC Time Stamp 03 SEP 2020 19:11
PC Open Date & Time 03 SEP 2020 16:11
PC Close Date & Time 04 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

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	98.7 °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	04 SEP 2020 19:07
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

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	98.2 °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	05 SEP 2020 19:22
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °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	06 SEP 2020 19:19
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

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	99.2 °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	07 SEP 2020 18:44
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

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	98.2 °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 19:13
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °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 SEP 2020 19:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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 13:09

PC Open Date & Time

03 SEP 2020 12:46

PC Close Date & Time

03 SEP 2020 15:16

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

03 SEP 2020 19:11

PC Open Date & Time

03 SEP 2020 16:11

PC Close Date & Time

04 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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	04 SEP 2020 19:08
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

05 SEP 2020 19:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

06 SEP 2020 19:19

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

07 SEP 2020 18:44

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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 19:13

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

09 SEP 2020 19:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

No

Yes

PC Time stamp	03 SEP 2020 13:12
PC Open Date & Time	03 SEP 2020 12:46
PC Close Date & Time	03 SEP 2020 15:16

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

No
Yes

PC Time stamp	03 SEP 2020 19:12
PC Open Date & Time	03 SEP 2020 16:11
PC Close Date & Time	04 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 19:09
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 19:23
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 19:20
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 18:45
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 19:14
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 19:02
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3062118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 01 OCT 2020

Time of assessment (00:00-23:59) 11:14 (24 HR)

Vital Signs Date and Time (derived) 01 OCT 2020 11:14

Temperature (xxx.x) 99.3 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 60 beats/min

Pulse units BPM

Respiratory Rate (xxx) 14 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 100 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 62 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3062118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

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.

US3062118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Was the sample collected? Yes No

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

Collection time (*00:00-23:59*) 11:24 (24 HR)

Collection date and time (derived) 01 OCT 2020 11:24

US3062118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:27:30

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 OCT 2020 10:58:57
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 16 OCT 2020 11:27:26

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

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

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 23 OCT 2020 17:14:13

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

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

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 03 NOV 2020 07:29:11

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

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

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 11 NOV 2020 11:22:51

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

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

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 <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 NOV 2020 07:12:51
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 24 NOV 2020 11:43:17

Patient Cloud Open Date & Time 21 NOV 2020 00:01

Patient Cloud Close Date & Time 25 NOV 2020 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 16:51:26
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 11:20:52
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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	16 DEC 2020 11:43:47
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 11:13:08
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 11:37:45

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 04 JAN 2021 16:51:11

Patient Cloud Open Date & Time 02 JAN 2021 00:01

Patient Cloud Close Date & Time 06 JAN 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 17:43:28
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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	16 JAN 2021 08:37:24
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 23 JAN 2021 05:19:04

Patient Cloud Open Date & Time 23 JAN 2021 00:01

Patient Cloud Close Date & Time 27 JAN 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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	31 JAN 2021 17:03:46
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 05:43:45
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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	15 FEB 2021 11:01:51
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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	21 FEB 2021 20:40:51
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 27 FEB 2021 06:46:47

Patient Cloud Open Date & Time 27 FEB 2021 00:01

Patient Cloud Close Date & Time 03 MAR 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 05:23:44
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 13:31:28
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 229

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

No

Yes

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

No

Yes

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

Date and time of submission 22 MAR 2021 12:49:34

Patient Cloud Open Date & Time 20 MAR 2021 00:01

Patient Cloud Close Date & Time 24 MAR 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 236

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

No

Yes

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

No

Yes

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

Date and time of submission 27 MAR 2021 06:47:42

Patient Cloud Open Date & Time 27 MAR 2021 00:01

Patient Cloud Close Date & Time 31 MAR 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 09:08:25
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 250

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

No

Yes

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

No

Yes

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

Date and time of submission 10 APR 2021 07:54:22

Patient Cloud Open Date & Time 10 APR 2021 00:01

Patient Cloud Close Date & Time 14 APR 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 07:47:43
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 26 APR 2021 11:32:44

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

Date and time of submission 03 MAY 2021 10:13:27

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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°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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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°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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 740

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

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

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

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

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

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

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3062118

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:02:24

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 06:47:09

US3062118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 22:11:40

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 22:11:40

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 3 MAR 2021

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

Folder OID VISIT4

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:13 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 10:13
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062118

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 15:52:45

Generated On: 09 Jun 2021 15:02:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

03 MAR 2021

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

US3062118

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 3 MAR 2021

Collection time (*00:00-23:59*) 10:20 (24 HR)

Collection date and time (derived) 3 MAR 2021 10:20

US3062118

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

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 _____

US3062118

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3062118

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:02:24

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3062118

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:02:24

Generate Next COVID-19 Assessment

Yes

No

US3062118

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 30 JAN 2021

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

Folder OID UNBLND_DECIDE

US3062118

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Date of updated informed consent (<i>dd MMM yyyy</i>)	30 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>)	30 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

US3062118

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Height	167.0 cm
Weight	75.9 kg
BMI (xxx.x)	27.21503

US3062118

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Height	167.0 cm
Weight	75.9 kg
BMI (xxx.x)	27.21503
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)	30 JAN 2021
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	30 JAN 2021 13:02
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3062118

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Height	167.0 cm
Weight	75.9 kg
BMI (xxx.x)	27.21503
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)	30 JAN 2021
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	30 JAN 2021 14:11
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3062118

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

30 JAN 2021

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

US3062118

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

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) 30 JAN 2021

What was the treatment time? (00:00-23:59) 13:38 (24 HR)

Treatment Date and Time (derived) 30 JAN 2021 13:38

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

US3062118

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 30 JAN 2021

Collection time (*00:00-23:59*) 13:05 (24 HR)

Collection date and time (derived) 30 JAN 2021 13:05

US3062118

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 30 JAN 2021

Collection time (*00:00 - 23:59*) 13:05

Collection Date and Time (derived) 30 JAN 2021 13:05

US3062118

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 22:11:40

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 22:11:40

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 3 MAR 2021

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

Folder OID OLD29

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

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>)	3 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:13 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 10:13
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

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>)	3 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:53 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 11:53
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	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>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3062118

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

3 MAR 2021

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

US3062118

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

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) 3 MAR 2021

What was the treatment time? (00:00-23:59) 11:21 (24 HR)

Treatment Date and Time (derived) 3 MAR 2021 11:21

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

US3062118

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 22:11:40

Generated On: 09 Jun 2021 15:02:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3062118

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 22:11:40

Generated On: 09 Jun 2021 15:02:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3062118

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 31 MAR 2021

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

Folder OID OLD57

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 31 MAR 2021

Time of assessment (*00:00-23:59*) 10:07 (24 HR)

Vital Signs Date and Time (derived) 31 MAR 2021 10:07

Temperature (*xxx.x*) 36.7 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) 64 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 110 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 67 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3062118

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

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.

US3062118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 31 MAR 2021

Collection time (*00:00-23:59*) 10:18 (24 HR)

Collection date and time (derived) 31 MAR 2021 10:18

US3062118

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Apr 2021 17:03:47

Generated On: 09 Jun 2021 15:02:24

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

AEID USA-US090-2021-MRNA-1273-P30
1000013

Adverse event WORSENING ARTHRITIS RIGHT
KNEE

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) 20 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 20 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 20 APR 2021

Hospital Discharge Date (dd MMM yyyy) 21 APR 2021

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003 338 of 1804
EAB) (1725)

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

DURING SUBJECT DAY 269
SAFETY CALL SUBJECT
REPORTED HAVING A RIGHT
KNEE REPLACEMENT. SUBJECT
RECEIVED KNEE
REPLACEMENT FOR
WORSENING ARTHRITIS OF
RIGHT KNEE, PROCEDURE
PERFORMED AT NMC HEALTH.
SUBJECT UNSURE OF
MEDICATIONS SHE RECEIVED
IN THE HOSPITAL AT THIS
TIME. SOURCE AND EDC
UPDATED. RELEASE OF
RECORDS HAS BEEN SENT TO
SUBJECT FOR SIGNATURE.

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

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

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

Yes

No

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

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication NUTRITIONAL SUPPLEMENT

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)

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US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:32:51

Generated On: 09 Jun 2021 15:02:24

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 01 JAN 2018

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3062118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 17:03:47

Generated On: 09 Jun 2021 15:02:24

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3062118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 17:03:47

Generated On: 09 Jun 2021 15:02:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
20 APR 2021	RIGHT KNEE REPLACEMENT	Adverse Event	

US3062118

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:02:24

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

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

SAEID	USA-US090-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:02:24

SAEID	USA-US090-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/APR/2021 17:13
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

US3062118 (Prod: Alliance for Multispecialty Research, LLC)

US3062118

Form: Participant Creation

Generated On: 09 Jun 2021 15:02:24

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'US3062118'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:30

US3062118

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	06 Aug 2020 17:54:14
	(b) (4)	

US3062118

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:31

US3062118

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Clinic (Clinic)'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:54:14

US3062118

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User entered 'SCRN'	System	06 Aug 2020 17:54:14

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:32

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '70'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:18:24

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered 'YEARS'	System	07 Aug 2020 15:18:24

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered '70'	System	06 Aug 2020 17:54:27

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Female (F)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:18:24

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Colton King (b) (4)	07 Aug 2020 15:18:24
	(b) (4)	

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '1'	Colton King (b) (4)	07 Aug 2020 15:18:24
	(b) (4)	

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:18:24

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:18:24

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:18:24

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:18:24

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '0'	Colton King (b) (4)	07 Aug 2020 15:18:24
	(b) (4)	

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 15:18:24
	(b) (4)	

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '0'	Colton King (b) (4)	07 Aug 2020 15:18:24
	(b) (4)	

US3062118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:02:24

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	Colton King (b) (4)	07 Aug 2020 15:18:24

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 Aug 2020'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:54:27

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered 'Aug 2020'	System	06 Aug 2020 17:54:27

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered '2020'	System	06 Aug 2020 17:54:27

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Amendment 1 (1)'	Riley King (b) (4)	06 Aug 2020 17:54:27
	(b) (4)	

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	06 Aug 2020 17:54:27
	(b) (4)	

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Riley King (b) (4)	06 Aug 2020 17:54:27
	(b) (4)	

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:54:27

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:54:27

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:31

US3062118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:02:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered '1'	System	06 Aug 2020 17:54:32

US3062118

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:54:32

US3062118

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:02:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	07 Aug 2020 14:48:56

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:51:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:51:17
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 14:50:24
User entered 'Seasonal Allergies'	Colton King (b) (4)	07 Aug 2020 14:49:39
	(b) (4)	

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '01 Apr 2018'	(b) (4) Colton King (b) (4)	07 Aug 2020 14:49:39

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4) (b) (4)	07 Aug 2020 14:49:39

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	07 Aug 2020 14:49:39

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	07 Aug 2020 14:49:39

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '0'	Colton King (b) (4)	07 Aug 2020 14:49:39
	(b) (4)	

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered 'Apr 2018'	System	07 Aug 2020 14:49:39

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered '2018'	System	07 Aug 2020 14:49:39

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered empty.	System	07 Aug 2020 14:49:39

US3062118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered empty.	System	07 Aug 2020 14:49:39

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 15:16:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 15:16:13
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 15:15:05
User entered 'Postmenopausal'	Colton King (b) (4)	07 Aug 2020 15:14:36
	(b) (4)	

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '01 Jan 2000'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:14:36

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:14:36

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:14:36
	(b) (4)	

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	07 Aug 2020 15:14:36

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	Colton King (b) (4)	07 Aug 2020 15:14:36

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered 'Jan 2000'	System	07 Aug 2020 15:14:36

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered '2000'	System	07 Aug 2020 15:14:36

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered empty.	System	07 Aug 2020 15:14:36

US3062118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User entered empty.	System	07 Aug 2020 15:14:36

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	07 Aug 2020 15:16:57
	(b) (4)	

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '06 Aug 2020'	Colton King (b) (4)	07 Aug 2020 15:16:57
	(b) (4)	

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '11:09'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:16:57

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User entered '06 Aug 2020 11:09'	System	07 Aug 2020 15:16:57

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '167.0' cm	(b) (4) Colton King (b) (4)	07 Aug 2020 15:16:57
DataPoint set to visible.	(b) (4) System	06 Aug 2020 17:54:32

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '74' kg	(b) (4) Colton King (b) (4)	07 Aug 2020 15:16:57
DataPoint set to visible.	(b) (4) System	06 Aug 2020 17:54:32

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
Amendment Manager: User entered '26.53376'	System	16 Sep 2020 23:45:43
User entered '26.5'	System	07 Aug 2020 15:16:57
DataPoint set to visible.	System	06 Aug 2020 17:54:32

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User entered 'kg/m2'	System	07 Aug 2020 15:16:57
DataPoint set to visible.	System	06 Aug 2020 17:54:32

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:19
	(b) (4)	
User entered '98.3' F	Colton King (b) (4)	07 Aug 2020 15:16:57
	(b) (4)	

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:19
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	07 Aug 2020 15:16:57
	(b) (4)	

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	07 Aug 2020 15:16:57

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:19
User entered '64'	(b) (4)	
	Colton King (b) (4)	07 Aug 2020 15:16:57
	(b) (4)	

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User entered 'bpm'	System	07 Aug 2020 15:16:57

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:19
User entered '14'	(b) (4)	
	Colton King (b) (4)	07 Aug 2020 15:16:57
	(b) (4)	

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User entered 'breaths/min'	System	07 Aug 2020 15:16:57

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:19
User entered '100'	(b) (4)	
	Colton King (b) (4)	07 Aug 2020 15:16:57
	(b) (4)	

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User entered 'mmHg'	System	07 Aug 2020 15:16:57

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:19
User entered '65'	(b) (4)	
	Colton King (b) (4)	07 Aug 2020 15:16:57
	(b) (4)	

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User entered 'mmHg'	System	07 Aug 2020 15:16:57

US3062118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37

US3062118

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:39
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	07 Aug 2020 15:17:04
	(b) (4)	

US3062118

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Sep 2020 13:21:08
User entered '06 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:39
User entered empty.	Colton King (b) (4)	07 Aug 2020 15:17:04

US3062118

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 Aug 2020'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:21:19

US3062118

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:02:24

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:21:19

US3062118

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:02:24

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Colton King (b) (4)	07 Aug 2020 15:21:19
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:02:24

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	07 Aug 2020 15:21:19

US3062118

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 15:21:19
	(b) (4)	

US3062118

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:02:24

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:21:19

US3062118

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '01 Jan 2000' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Sep 2020 01:04:34
	(b) (4)	
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	07 Aug 2020 15:22:21
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	07 Aug 2020 15:21:19
User entered empty.	Colton King (b) (4)	07 Aug 2020 15:21:19
	(b) (4)	

US3062118

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:02:24

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:36
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User closed query 'Per DM CLR: Date of last menstruation unknown = YES, however, the corresponding MedHistory condition has a start date of 01 JAN 2000. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 10:59:09
Query 'Per DM CLR: Date of last menstruation unknown = YES, however, the corresponding MedHistory condition has a start date of 01 JAN 2000. Please reconcile and update as appropriate, otherwise provide clarification.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 01:04:38
User entered '0' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 01:04:34
User opened query 'Per DM CLR: Date of last menstruation unknown = YES, however, the corresponding MedHistory condition has a start date of 01 JAN 2000. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 05:43:30
User entered '1' reason for change: Data Entry Error	Colton King (b) (4)	07 Aug 2020 15:22:21
User entered '0'	Colton King (b) (4)	07 Aug 2020 15:21:19

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	07 Aug 2020 15:17:58
	(b) (4)	

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	07 Aug 2020 15:17:58
	(b) (4)	

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	07 Aug 2020 15:17:58
	(b) (4)	

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

US3062118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	07 Aug 2020 15:17:58
	(b) (4)	

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 15:17:58
	(b) (4)	

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '1'	Colton King (b) (4)	07 Aug 2020 15:17:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

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)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '0'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '0'	Colton King (b) (4)	07 Aug 2020 15:17:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '0'	Colton King (b) (4)	07 Aug 2020 15:17:58
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:02:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:14:37
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	07 Aug 2020 15:17:58

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	06 Aug 2020 17:54:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '06 Aug 2020'	Riley King (b) (4)	06 Aug 2020 17:54:59
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Clinic (Clinic)'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:54:59

US3062118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'VISIT1'	System	06 Aug 2020 17:54:59

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:14:29

US3062118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:02:24

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:34:01
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:34:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 17:14:29
User entered '184882' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:14:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:02:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:14:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:02:24

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:55:22

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:02:24

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	06 Aug 2020 17:55:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:02:24

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	06 Aug 2020 17:55:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:02:24

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:55:22

US3062118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:02:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:55:22

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:27:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4) (b) (4)	26 Aug 2020 17:08:29
User entered '167.0' cm	Colton King (b) (4) (b) (4)	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:29
	(b) (4)	
User entered '74.0' kg	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:29
	(b) (4)	
User entered '167.0' cm	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:29
	(b) (4)	
User entered '74.0' kg	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	07 Aug 2020 15:25:48

b

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 Aug 2020'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '11:09'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '06 Aug 2020 11:09'	System	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '98.3' F	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '64'	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'bpm'	System	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '14'	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'breaths/min'	System	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '100'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '65'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:29
	(b) (4)	
User entered '167.0' cm	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:29
	(b) (4)	
User entered '74.0' kg	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	07 Aug 2020 15:25:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 Aug 2020'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
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)	12 Aug 2020 07:04:10
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Correct per protocol' (Site from System).	Colton King (b) (4)	07 Aug 2020 15:26:03
	(b) (4)	
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 15:25:48
User entered '13:11'	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '06 Aug 2020 13:11'	System	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	21 Sep 2020 07:45:18
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Sherry Henning (b) (4)	19 Sep 2020 02:02:56
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:45:43
User entered '96.1' F	Colton King (b) (4)	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Oral (Oral)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '57'	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'bpm'	System	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '16'	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'breaths/min'	System	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '108'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '64'	Colton King (b) (4)	07 Aug 2020 15:25:48
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	07 Aug 2020 15:25:48

US3062118

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 17:08:46
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	07 Aug 2020 15:26:25
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty; reason for change Data Entry Error	(b) (4) Brianna Burton (b) (4)	26 Aug 2020 17:08:46
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Aug 2020 15:26:40
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	07 Aug 2020 15:26:40
User entered '06 Aug 2020' reason for change: Data Entry Error	Colton King (b) (4)	07 Aug 2020 15:26:40
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Aug 2020 15:26:25
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	07 Aug 2020 15:26:25
User entered '06 Jul 2020'	Colton King (b) (4)	07 Aug 2020 15:26:25

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:55:41

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:55:41

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	06 Aug 2020 17:55:41

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 17:55:41

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 Aug 2020'	(b) (4) Riley King (b) (4)	06 Aug 2020 17:55:41

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '12:39'	Riley King (b) (4)	06 Aug 2020 17:55:41
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '06 Aug 2020 12:39'	System	06 Aug 2020 17:55:41

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Riley King (b) (4)	06 Aug 2020 17:55:41
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'ONCE'	System	06 Aug 2020 17:55:41

US3062118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 17:55:41

US3062118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:27:19

US3062118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 Aug 2020'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:27:19

US3062118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '11:27'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:27:19

US3062118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '06 Aug 2020 11:27'	System	07 Aug 2020 15:27:19

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:02:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '06 Aug 2020'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:27:37
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:02:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colton King (b) (4) (b) (4)	07 Aug 2020 15:27:37

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	07 Aug 2020 15:27:37
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '11:31'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:27:37

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '06 Aug 2020 11:31'	System	07 Aug 2020 15:27:37

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:02:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colton King (b) (4) (b) (4)	07 Aug 2020 15:27:37

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	07 Aug 2020 15:27:37
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 15:27:37
	(b) (4)	

US3062118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered empty.	System	07 Aug 2020 15:27:37

US3062118

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	07 Aug 2020 15:29:31

US3062118

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'I'	System	07 Aug 2020 15:29:31

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:16:29', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '74567e04-463c-42cb-8f1d-996bab446f60'	System	06 Aug 2020 18:17:08
User entered 'Yes (Y)'	System	06 Aug 2020 18:17:08

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:16:42', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '74567e04-463c-42cb-8f1d-996bab446f60'	System	06 Aug 2020 18:17:08
User entered '96.1'	System	06 Aug 2020 18:17:08

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:16:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '74567e04-463c-42cb-8f1d-996bab446f60'	System	06 Aug 2020 18:17:08
User entered 'No (N)'	System	06 Aug 2020 18:17:08

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:17:06', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '74567e04-463c-42cb-8f1d-996bab446f60'	System	06 Aug 2020 18:17:08
User entered '06 Aug 2020 13:17'	System	06 Aug 2020 18:17:08

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 12:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 15:29'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:38:12', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c3cb624a-efde-4627-9359-25d8879896f1'	System	07 Aug 2020 10:38:44
User entered 'Yes (Y)'	System	07 Aug 2020 10:38:44

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:38:25', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c3cb624a-efde-4627-9359-25d8879896f1'	System	07 Aug 2020 10:38:44
User entered '97.8'	System	07 Aug 2020 10:38:44

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:38:31', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c3cb624a-efde-4627-9359-25d8879896f1'	System	07 Aug 2020 10:38:44
User entered 'No (N)'	System	07 Aug 2020 10:38:44

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:38:42', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c3cb624a-efde-4627-9359-25d8879896f1'	System	07 Aug 2020 10:38:44
User entered '07 Aug 2020 05:38'	System	07 Aug 2020 10:38:44

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 16:24'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 2'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:32:52', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '9b9adc59-adf6-4c13-bdc0-95f246621fc0'	System	08 Aug 2020 09:33:38
User entered 'Yes (Y)'	System	08 Aug 2020 09:33:38

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:33:10', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '9b9adc59-adf6-4c13-bdc0-95f246621fc0'	System	08 Aug 2020 09:33:38
User entered '97.6'	System	08 Aug 2020 09:33:38

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:33:22', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '9b9adc59-adf6-4c13-bdc0-95f246621fc0'	System	08 Aug 2020 09:33:38
User entered 'No (N)'	System	08 Aug 2020 09:33:38

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:33:34', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '9b9adc59-adf6-4c13-bdc0-95f246621fc0'	System	08 Aug 2020 09:33:38
User entered '08 Aug 2020 04:33'	System	08 Aug 2020 09:33:38

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 3'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:21:10', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '785375fc-83cd-4a30-b817-bb361b737f26'	System	09 Aug 2020 10:21:36
User entered 'Yes (Y)'	System	09 Aug 2020 10:21:36

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:21:22', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '785375fc-83cd-4a30-b817-bb361b737f26'	System	09 Aug 2020 10:21:36
User entered '97.3'	System	09 Aug 2020 10:21:36

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:21:26', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '785375fc-83cd-4a30-b817-bb361b737f26'	System	09 Aug 2020 10:21:36
User entered 'No (N)'	System	09 Aug 2020 10:21:36

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:21:34', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '785375fc-83cd-4a30-b817-bb361b737f26'	System	09 Aug 2020 10:21:36
User entered '09 Aug 2020 05:21'	System	09 Aug 2020 10:21:36

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 4'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:19:06', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e86c9fb8-6f10-4655-a3c7-dc25bbac5839'	System	10 Aug 2020 10:20:05
User entered 'Yes (Y)'	System	10 Aug 2020 10:20:05

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:19:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e86c9fb8-6f10-4655-a3c7-dc25bbac5839'	System	10 Aug 2020 10:20:05
User entered '98.2'	System	10 Aug 2020 10:20:05

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:19:55', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e86c9fb8-6f10-4655-a3c7-dc25bbac5839'	System	10 Aug 2020 10:20:05
User entered 'No (N)'	System	10 Aug 2020 10:20:05

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:02', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e86c9fb8-6f10-4655-a3c7-dc25bbac5839'	System	10 Aug 2020 10:20:05
User entered '10 Aug 2020 05:20'	System	10 Aug 2020 10:20:05

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 5'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:14:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '9040afee-df5e-42e0-9c67-2a15b9be570a'	System	11 Aug 2020 10:15:36
User entered 'Yes (Y)'	System	11 Aug 2020 10:15:36

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:16', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '9040afee-df5e-42e0-9c67-2a15b9be570a'	System	11 Aug 2020 10:15:36
User entered '97.5'	System	11 Aug 2020 10:15:36

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:21', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '9040afee-df5e-42e0-9c67-2a15b9be570a'	System	11 Aug 2020 10:15:36
User entered 'No (N)'	System	11 Aug 2020 10:15:36

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:29', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '9040afee-df5e-42e0-9c67-2a15b9be570a'	System	11 Aug 2020 10:15:36
User entered '11 Aug 2020 05:15'	System	11 Aug 2020 10:15:36

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 6'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:19:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'eda77ef3-1021-4055-accd-4edd61129308'	System	12 Aug 2020 10:20:16
User entered 'Yes (Y)'	System	12 Aug 2020 10:20:16

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:20:07', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'eda77ef3-1021-4055-accd-4edd61129308'	System	12 Aug 2020 10:20:16
User entered '98.0'	System	12 Aug 2020 10:20:16

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:20:10', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'eda77ef3-1021-4055-accd-4edd61129308'	System	12 Aug 2020 10:20:16
User entered 'No (N)'	System	12 Aug 2020 10:20:16

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:20:15', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'eda77ef3-1021-4055-accd-4edd61129308'	System	12 Aug 2020 10:20:16
User entered '12 Aug 2020 05:20'	System	12 Aug 2020 10:20:16

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 7'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:53:41', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ba927c73-f7f4-4224-b47f-5dadcaeb3228'	System	13 Aug 2020 10:54:44
User entered 'Yes (Y)'	System	13 Aug 2020 10:54:44

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:08', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ba927c73-f7f4-4224-b47f-5dadcaeb3228'	System	13 Aug 2020 10:54:44
User entered '97.6'	System	13 Aug 2020 10:54:44

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:12', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ba927c73-f7f4-4224-b47f-5dadcaeb3228'	System	13 Aug 2020 10:54:44
User entered 'No (N)'	System	13 Aug 2020 10:54:44

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:17', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ba927c73-f7f4-4224-b47f-5dadcaeb3228'	System	13 Aug 2020 10:54:44
User entered '13 Aug 2020 05:54'	System	13 Aug 2020 10:54:44

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:17:25', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c6b97070-b64f-45e7-a589-1989558b7a8f'	System	06 Aug 2020 18:18:03
User entered 'None (1)'	System	06 Aug 2020 18:18:03

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:17:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c6b97070-b64f-45e7-a589-1989558b7a8f'	System	06 Aug 2020 18:18:03
User entered 'No (N)'	System	06 Aug 2020 18:18:03

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:17:40', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c6b97070-b64f-45e7-a589-1989558b7a8f'	System	06 Aug 2020 18:18:03
User entered 'No (N)'	System	06 Aug 2020 18:18:03

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:17:50', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c6b97070-b64f-45e7-a589-1989558b7a8f'	System	06 Aug 2020 18:18:03
User entered 'None (1)'	System	06 Aug 2020 18:18:03

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'c6b97070-b64f-45e7-a589-1989558b7a8f'	System	06 Aug 2020 18:18:03
User entered '06 Aug 2020 13:18'	System	06 Aug 2020 18:18:03

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 12:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 15:29'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:38:59', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '18c4eb65-5beb-435e-b4fd-e915c17c9466'	System	07 Aug 2020 10:39:34
User entered 'None (1)'	System	07 Aug 2020 10:39:34

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:07', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '18c4eb65-5beb-435e-b4fd-e915c17c9466'	System	07 Aug 2020 10:39:34
User entered 'No (N)'	System	07 Aug 2020 10:39:34

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:14', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '18c4eb65-5beb-435e-b4fd-e915c17c9466'	System	07 Aug 2020 10:39:34
User entered 'No (N)'	System	07 Aug 2020 10:39:34

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:19', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '18c4eb65-5beb-435e-b4fd-e915c17c9466'	System	07 Aug 2020 10:39:34
User entered 'None (1)'	System	07 Aug 2020 10:39:34

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '18c4eb65-5beb-435e-b4fd-e915c17c9466'	System	07 Aug 2020 10:39:34
User entered '07 Aug 2020 05:39'	System	07 Aug 2020 10:39:34

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 16:24'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 2'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:19', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '1d211c1e-b54a-4f02-8dc3-e3ca69b5850a'	System	08 Aug 2020 09:34:30
User entered 'None (1)'	System	08 Aug 2020 09:34:30

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:33:59', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '1d211c1e-b54a-4f02-8dc3-e3ca69b5850a'	System	08 Aug 2020 09:34:30
User entered 'No (N)'	System	08 Aug 2020 09:34:30

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:03', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '1d211c1e-b54a-4f02-8dc3-e3ca69b5850a'	System	08 Aug 2020 09:34:30
User entered 'No (N)'	System	08 Aug 2020 09:34:30

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:11', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '1d211c1e-b54a-4f02-8dc3-e3ca69b5850a'	System	08 Aug 2020 09:34:30
User entered 'None (1)'	System	08 Aug 2020 09:34:30

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:26', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '1d211c1e-b54a-4f02-8dc3-e3ca69b5850a'	System	08 Aug 2020 09:34:30
User entered '08 Aug 2020 04:34'	System	08 Aug 2020 09:34:30

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 3'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:21:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'aa2d247a-f604-4c03-801a-774ff5ea3ef6'	System	09 Aug 2020 10:22:12
User entered 'None (1)'	System	09 Aug 2020 10:22:12

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:21:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'aa2d247a-f604-4c03-801a-774ff5ea3ef6'	System	09 Aug 2020 10:22:12
User entered 'No (N)'	System	09 Aug 2020 10:22:12

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:21:54', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'aa2d247a-f604-4c03-801a-774ff5ea3ef6'	System	09 Aug 2020 10:22:12
User entered 'No (N)'	System	09 Aug 2020 10:22:12

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:01', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'aa2d247a-f604-4c03-801a-774ff5ea3ef6'	System	09 Aug 2020 10:22:12
User entered 'None (1)'	System	09 Aug 2020 10:22:12

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:08', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'aa2d247a-f604-4c03-801a-774ff5ea3ef6'	System	09 Aug 2020 10:22:12
User entered '09 Aug 2020 05:22'	System	09 Aug 2020 10:22:12

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 4'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:11', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e8d12742-0469-4f66-8647-f4fff62c676e'	System	10 Aug 2020 10:20:33
User entered 'None (1)'	System	10 Aug 2020 10:20:33

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:15', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e8d12742-0469-4f66-8647-f4fff62c676e'	System	10 Aug 2020 10:20:33
User entered 'No (N)'	System	10 Aug 2020 10:20:33

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:18', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e8d12742-0469-4f66-8647-f4fff62c676e'	System	10 Aug 2020 10:20:33
User entered 'No (N)'	System	10 Aug 2020 10:20:33

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:25', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e8d12742-0469-4f66-8647-f4fff62c676e'	System	10 Aug 2020 10:20:33
User entered 'None (1)'	System	10 Aug 2020 10:20:33

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:31', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e8d12742-0469-4f66-8647-f4fff62c676e'	System	10 Aug 2020 10:20:33
User entered '10 Aug 2020 05:20'	System	10 Aug 2020 10:20:33

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 5'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:40', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '61fbc789-2122-47a2-b516-35898829ff24'	System	11 Aug 2020 10:15:57
User entered 'None (1)'	System	11 Aug 2020 10:15:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '61fbc789-2122-47a2-b516-35898829ff24'	System	11 Aug 2020 10:15:57
User entered 'No (N)'	System	11 Aug 2020 10:15:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:46', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '61fbc789-2122-47a2-b516-35898829ff24'	System	11 Aug 2020 10:15:57
User entered 'No (N)'	System	11 Aug 2020 10:15:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:49', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '61fbc789-2122-47a2-b516-35898829ff24'	System	11 Aug 2020 10:15:57
User entered 'None (1)'	System	11 Aug 2020 10:15:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '61fbc789-2122-47a2-b516-35898829ff24'	System	11 Aug 2020 10:15:57
User entered '11 Aug 2020 05:15'	System	11 Aug 2020 10:15:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 6'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:20:25', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f5a3bdf9-4c2c-4605-88a6-290c1cae4565'	System	12 Aug 2020 10:20:57
User entered 'None (1)'	System	12 Aug 2020 10:20:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:20:46', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f5a3bdf9-4c2c-4605-88a6-290c1cae4565'	System	12 Aug 2020 10:20:57
User entered 'No (N)'	System	12 Aug 2020 10:20:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:20:34', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f5a3bdf9-4c2c-4605-88a6-290c1cae4565'	System	12 Aug 2020 10:20:57
User entered 'No (N)'	System	12 Aug 2020 10:20:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:20:40', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f5a3bdf9-4c2c-4605-88a6-290c1cae4565'	System	12 Aug 2020 10:20:57
User entered 'None (1)'	System	12 Aug 2020 10:20:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:20:52', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f5a3bdf9-4c2c-4605-88a6-290c1cae4565'	System	12 Aug 2020 10:20:57
User entered '12 Aug 2020 05:20'	System	12 Aug 2020 10:20:57

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 7'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:23', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4b93a306-83c9-4005-9315-b13dcd50e1f1'	System	13 Aug 2020 10:54:45
User entered 'None (1)'	System	13 Aug 2020 10:54:45

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:26', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4b93a306-83c9-4005-9315-b13dcd50e1f1'	System	13 Aug 2020 10:54:45
User entered 'No (N)'	System	13 Aug 2020 10:54:45

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:29', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4b93a306-83c9-4005-9315-b13dcd50e1f1'	System	13 Aug 2020 10:54:45
User entered 'No (N)'	System	13 Aug 2020 10:54:45

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:34', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4b93a306-83c9-4005-9315-b13dcd50e1f1'	System	13 Aug 2020 10:54:45
User entered 'None (1)'	System	13 Aug 2020 10:54:45

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4b93a306-83c9-4005-9315-b13dcd50e1f1'	System	13 Aug 2020 10:54:45
User entered '13 Aug 2020 05:54'	System	13 Aug 2020 10:54:45

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:18', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f597f3c1-1418-4044-9c7c-7d8647dc5530'	System	06 Aug 2020 18:18:52
User entered 'None (0)'	System	06 Aug 2020 18:18:52

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:24', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f597f3c1-1418-4044-9c7c-7d8647dc5530'	System	06 Aug 2020 18:18:52
User entered 'None (0)'	System	06 Aug 2020 18:18:52

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:28', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f597f3c1-1418-4044-9c7c-7d8647dc5530'	System	06 Aug 2020 18:18:52
User entered 'None (0)'	System	06 Aug 2020 18:18:52

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:32', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f597f3c1-1418-4044-9c7c-7d8647dc5530'	System	06 Aug 2020 18:18:52
User entered 'None (0)'	System	06 Aug 2020 18:18:52

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:35', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f597f3c1-1418-4044-9c7c-7d8647dc5530'	System	06 Aug 2020 18:18:52
User entered 'None (0)'	System	06 Aug 2020 18:18:52

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:39', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f597f3c1-1418-4044-9c7c-7d8647dc5530'	System	06 Aug 2020 18:18:52
User entered 'None (0)'	System	06 Aug 2020 18:18:52

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f597f3c1-1418-4044-9c7c-7d8647dc5530'	System	06 Aug 2020 18:18:52
User entered 'No (N)'	System	06 Aug 2020 18:18:52

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-06T13:18:50', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f597f3c1-1418-4044-9c7c-7d8647dc5530'	System	06 Aug 2020 18:18:52
User entered '06 Aug 2020 13:18'	System	06 Aug 2020 18:18:52

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 12:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 15:29'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8707277-0ce7-4e48-9f83-325ab3c968c0'	System	07 Aug 2020 10:40:16
User entered 'None (0)'	System	07 Aug 2020 10:40:16

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:41', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8707277-0ce7-4e48-9f83-325ab3c968c0'	System	07 Aug 2020 10:40:16
User entered 'None (0)'	System	07 Aug 2020 10:40:16

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:46', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8707277-0ce7-4e48-9f83-325ab3c968c0'	System	07 Aug 2020 10:40:16
User entered 'None (0)'	System	07 Aug 2020 10:40:16

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:49', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8707277-0ce7-4e48-9f83-325ab3c968c0'	System	07 Aug 2020 10:40:16
User entered 'None (0)'	System	07 Aug 2020 10:40:16

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8707277-0ce7-4e48-9f83-325ab3c968c0'	System	07 Aug 2020 10:40:16
User entered 'None (0)'	System	07 Aug 2020 10:40:16

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:39:57', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8707277-0ce7-4e48-9f83-325ab3c968c0'	System	07 Aug 2020 10:40:16
User entered 'None (0)'	System	07 Aug 2020 10:40:16

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:40:02', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8707277-0ce7-4e48-9f83-325ab3c968c0'	System	07 Aug 2020 10:40:16
User entered 'No (N)'	System	07 Aug 2020 10:40:16

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-07T05:40:11', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8707277-0ce7-4e48-9f83-325ab3c968c0'	System	07 Aug 2020 10:40:16
User entered '07 Aug 2020 05:40'	System	07 Aug 2020 10:40:16

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Aug 2020 16:24'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 2'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:34', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8968264-d4dc-4777-b511-039fb9f2f1fa'	System	08 Aug 2020 09:35:07
User entered 'None (0)'	System	08 Aug 2020 09:35:07

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8968264-d4dc-4777-b511-039fb9f2f1fa'	System	08 Aug 2020 09:35:07
User entered 'None (0)'	System	08 Aug 2020 09:35:07

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:42', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8968264-d4dc-4777-b511-039fb9f2f1fa'	System	08 Aug 2020 09:35:07
User entered 'None (0)'	System	08 Aug 2020 09:35:07

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:45', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8968264-d4dc-4777-b511-039fb9f2f1fa'	System	08 Aug 2020 09:35:07
User entered 'None (0)'	System	08 Aug 2020 09:35:07

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:49', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8968264-d4dc-4777-b511-039fb9f2f1fa'	System	08 Aug 2020 09:35:07
User entered 'None (0)'	System	08 Aug 2020 09:35:07

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:52', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8968264-d4dc-4777-b511-039fb9f2f1fa'	System	08 Aug 2020 09:35:07
User entered 'None (0)'	System	08 Aug 2020 09:35:07

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:34:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8968264-d4dc-4777-b511-039fb9f2f1fa'	System	08 Aug 2020 09:35:07
User entered 'No (N)'	System	08 Aug 2020 09:35:07

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-08T04:35:05', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a8968264-d4dc-4777-b511-039fb9f2f1fa'	System	08 Aug 2020 09:35:07
User entered '08 Aug 2020 04:35'	System	08 Aug 2020 09:35:07

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 3'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:18', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7401e8a7-77af-4a9b-af25-2970dd6023c3'	System	09 Aug 2020 10:22:48
User entered 'None (0)'	System	09 Aug 2020 10:22:48

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:21', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7401e8a7-77af-4a9b-af25-2970dd6023c3'	System	09 Aug 2020 10:22:48
User entered 'None (0)'	System	09 Aug 2020 10:22:48

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:24', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7401e8a7-77af-4a9b-af25-2970dd6023c3'	System	09 Aug 2020 10:22:48
User entered 'None (0)'	System	09 Aug 2020 10:22:48

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:27', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7401e8a7-77af-4a9b-af25-2970dd6023c3'	System	09 Aug 2020 10:22:48
User entered 'None (0)'	System	09 Aug 2020 10:22:48

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7401e8a7-77af-4a9b-af25-2970dd6023c3'	System	09 Aug 2020 10:22:48
User entered 'None (0)'	System	09 Aug 2020 10:22:48

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:33', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7401e8a7-77af-4a9b-af25-2970dd6023c3'	System	09 Aug 2020 10:22:48
User entered 'None (0)'	System	09 Aug 2020 10:22:48

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:37', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7401e8a7-77af-4a9b-af25-2970dd6023c3'	System	09 Aug 2020 10:22:48
User entered 'No (N)'	System	09 Aug 2020 10:22:48

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-09T05:22:45', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7401e8a7-77af-4a9b-af25-2970dd6023c3'	System	09 Aug 2020 10:22:48
User entered '09 Aug 2020 05:22'	System	09 Aug 2020 10:22:48

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 4'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:37', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '85b79793-c130-4f2e-9fd3-809fd92fb68c'	System	10 Aug 2020 10:21:05
User entered 'None (0)'	System	10 Aug 2020 10:21:05

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:41', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '85b79793-c130-4f2e-9fd3-809fd92fb68c'	System	10 Aug 2020 10:21:05
User entered 'None (0)'	System	10 Aug 2020 10:21:05

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:44', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '85b79793-c130-4f2e-9fd3-809fd92fb68c'	System	10 Aug 2020 10:21:05
User entered 'None (0)'	System	10 Aug 2020 10:21:05

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:47', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '85b79793-c130-4f2e-9fd3-809fd92fb68c'	System	10 Aug 2020 10:21:05
User entered 'None (0)'	System	10 Aug 2020 10:21:05

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:49', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '85b79793-c130-4f2e-9fd3-809fd92fb68c'	System	10 Aug 2020 10:21:05
User entered 'None (0)'	System	10 Aug 2020 10:21:05

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:52', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '85b79793-c130-4f2e-9fd3-809fd92fb68c'	System	10 Aug 2020 10:21:05
User entered 'None (0)'	System	10 Aug 2020 10:21:05

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:20:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '85b79793-c130-4f2e-9fd3-809fd92fb68c'	System	10 Aug 2020 10:21:05
User entered 'No (N)'	System	10 Aug 2020 10:21:05

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-10T05:21:02', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '85b79793-c130-4f2e-9fd3-809fd92fb68c'	System	10 Aug 2020 10:21:05
User entered '10 Aug 2020 05:21'	System	10 Aug 2020 10:21:05

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 5'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:15:59', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e5c60603-9ded-4536-9592-95a7e8fed59d'	System	11 Aug 2020 10:16:22
User entered 'None (0)'	System	11 Aug 2020 10:16:22

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:16:02', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e5c60603-9ded-4536-9592-95a7e8fed59d'	System	11 Aug 2020 10:16:22
User entered 'None (0)'	System	11 Aug 2020 10:16:22

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:16:05', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e5c60603-9ded-4536-9592-95a7e8fed59d'	System	11 Aug 2020 10:16:22
User entered 'None (0)'	System	11 Aug 2020 10:16:22

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:16:07', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e5c60603-9ded-4536-9592-95a7e8fed59d'	System	11 Aug 2020 10:16:22
User entered 'None (0)'	System	11 Aug 2020 10:16:22

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:16:10', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e5c60603-9ded-4536-9592-95a7e8fed59d'	System	11 Aug 2020 10:16:22
User entered 'None (0)'	System	11 Aug 2020 10:16:22

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:16:12', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e5c60603-9ded-4536-9592-95a7e8fed59d'	System	11 Aug 2020 10:16:22
User entered 'None (0)'	System	11 Aug 2020 10:16:22

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:16:16', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e5c60603-9ded-4536-9592-95a7e8fed59d'	System	11 Aug 2020 10:16:22
User entered 'No (N)'	System	11 Aug 2020 10:16:22

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-11T05:16:19', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e5c60603-9ded-4536-9592-95a7e8fed59d'	System	11 Aug 2020 10:16:22
User entered '11 Aug 2020 05:16'	System	11 Aug 2020 10:16:22

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 6'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:21:05', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a2021e6a-b4a6-409c-be5f-05b233158dd4'	System	12 Aug 2020 10:21:27
User entered 'None (0)'	System	12 Aug 2020 10:21:27

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:21:08', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a2021e6a-b4a6-409c-be5f-05b233158dd4'	System	12 Aug 2020 10:21:27
User entered 'None (0)'	System	12 Aug 2020 10:21:27

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:21:10', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a2021e6a-b4a6-409c-be5f-05b233158dd4'	System	12 Aug 2020 10:21:27
User entered 'None (0)'	System	12 Aug 2020 10:21:27

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:21:13', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a2021e6a-b4a6-409c-be5f-05b233158dd4'	System	12 Aug 2020 10:21:27
User entered 'None (0)'	System	12 Aug 2020 10:21:27

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:21:16', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a2021e6a-b4a6-409c-be5f-05b233158dd4'	System	12 Aug 2020 10:21:27
User entered 'None (0)'	System	12 Aug 2020 10:21:27

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:21:18', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a2021e6a-b4a6-409c-be5f-05b233158dd4'	System	12 Aug 2020 10:21:27
User entered 'None (0)'	System	12 Aug 2020 10:21:27

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:21:23', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a2021e6a-b4a6-409c-be5f-05b233158dd4'	System	12 Aug 2020 10:21:27
User entered 'No (N)'	System	12 Aug 2020 10:21:27

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-12T05:21:25', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a2021e6a-b4a6-409c-be5f-05b233158dd4'	System	12 Aug 2020 10:21:27
User entered '12 Aug 2020 05:21'	System	12 Aug 2020 10:21:27

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 7'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '406df27d-8463-478f-b30e-0acf663e4666'	System	13 Aug 2020 10:55:06
User entered 'None (0)'	System	13 Aug 2020 10:55:06

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:46', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '406df27d-8463-478f-b30e-0acf663e4666'	System	13 Aug 2020 10:55:06
User entered 'None (0)'	System	13 Aug 2020 10:55:06

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:48', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '406df27d-8463-478f-b30e-0acf663e4666'	System	13 Aug 2020 10:55:06
User entered 'None (0)'	System	13 Aug 2020 10:55:06

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '406df27d-8463-478f-b30e-0acf663e4666'	System	13 Aug 2020 10:55:06
User entered 'None (0)'	System	13 Aug 2020 10:55:06

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:54', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '406df27d-8463-478f-b30e-0acf663e4666'	System	13 Aug 2020 10:55:06
User entered 'None (0)'	System	13 Aug 2020 10:55:06

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:54:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '406df27d-8463-478f-b30e-0acf663e4666'	System	13 Aug 2020 10:55:06
User entered 'None (0)'	System	13 Aug 2020 10:55:06

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:55:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '406df27d-8463-478f-b30e-0acf663e4666'	System	13 Aug 2020 10:55:06
User entered 'No (N)'	System	13 Aug 2020 10:55:06

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-08-13T05:55:04', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '406df27d-8463-478f-b30e-0acf663e4666'	System	13 Aug 2020 10:55:06
User entered '13 Aug 2020 05:55'	System	13 Aug 2020 10:55:06

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:55:41

US3062118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	14 Aug 2020 19:37:30
	(b) (4)	

US3062118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '14 Aug 2020'	(b) (4) Janna Martinez (b) (4)	14 Aug 2020 19:37:30
	(b) (4)	

US3062118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	14 Aug 2020 19:37:30

US3062118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Janna Martinez (b) (4)	14 Aug 2020 19:37:30
	(b) (4)	

US3062118

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	14 Aug 2020 19:37:20
	(b) (4)	

US3062118

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '1'	System	14 Aug 2020 19:37:20

US3062118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	20 Aug 2020 20:44:30
	(b) (4)	

US3062118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '20 Aug 2020'	(b) (4) Janna Martinez (b) (4)	20 Aug 2020 20:44:30
	(b) (4)	

US3062118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	20 Aug 2020 20:44:30
	(b) (4)	

US3062118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Janna Martinez (b) (4)	20 Aug 2020 20:44:30
	(b) (4)	

US3062118

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	20 Aug 2020 20:44:20
	(b) (4)	

US3062118

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'I'	System	20 Aug 2020 20:44:20

US3062118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	28 Aug 2020 22:11:02
	(b) (4)	

US3062118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '28 Aug 2020'	Sherry Henning (b) (4)	28 Aug 2020 22:11:02
	(b) (4)	

US3062118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	28 Aug 2020 22:11:02
	(b) (4)	

US3062118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Sherry Henning (b) (4)	28 Aug 2020 22:11:02

US3062118

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	28 Aug 2020 22:11:07
	(b) (4)	

US3062118

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'I'	System	28 Aug 2020 22:11:07

US3062118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	03 Sep 2020 17:37:21
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '3 Sep 2020'	Sherry Henning (b) (4)	03 Sep 2020 17:37:21
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	03 Sep 2020 17:38:07
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sherry Henning (b) (4)	03 Sep 2020 17:38:07
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	03 Sep 2020 17:37:21
User entered empty.	System	03 Sep 2020 17:37:21
	Sherry Henning (b) (4)	03 Sep 2020 17:37:21
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'VISIT2'	System	03 Sep 2020 17:37:21

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Sep 2020 13:49:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 13:49:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Sep 2020 13:47:42
User entered empty.	System	04 Sep 2020 13:47:42
	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '3 Sep 2020' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '11:25' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
User entered empty.	(b) (4)	
	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '3 Sep 2020 11:25'	System	04 Sep 2020 13:49:35
User entered empty.	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '98.4' F reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '64' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'bpm'	System	04 Sep 2020 13:49:35
User entered empty.	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '14' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'breaths/min'	System	04 Sep 2020 13:49:35
User entered empty.	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '99' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	04 Sep 2020 13:49:35
User entered empty.	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '60' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:49:35
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	04 Sep 2020 13:49:35
User entered empty.	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 13:47:59
User entered '03 Sep 2020' reason for change: Data Entry Error	Colton King (b) (4)	04 Sep 2020 13:47:59
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 13:47:42
User entered '4 Sep 2020'	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '13:04'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '03 Sep 2020 13:04'	System	04 Sep 2020 13:47:59
User entered '4 Sep 2020 13:04'	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '97.9' F	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Oral (Oral)'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '56'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'bpm'	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '16'	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'breaths/min'	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '111'	Colton King (b) (4)	04 Sep 2020 13:47:42
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '64'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	04 Sep 2020 13:47:42

US3062118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	04 Sep 2020 13:50:24
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '3 Sep 2020'	Colton King (b) (4)	04 Sep 2020 13:50:24
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4)	03 Sep 2020 17:39:12

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	03 Sep 2020 17:39:12
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Sherry Henning (b) (4)	03 Sep 2020 17:39:12

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 17:39:12

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '3 Sep 2020'	Sherry Henning (b) (4)	03 Sep 2020 17:39:12
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '12:26'	Sherry Henning (b) (4)	03 Sep 2020 17:39:12
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '3 Sep 2020 12:26'	System	03 Sep 2020 17:39:12

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4)	03 Sep 2020 17:39:12
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'ONCE'	System	03 Sep 2020 17:39:12

US3062118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 17:39:12

US3062118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:50:43

US3062118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '3 Sep 2020'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:50:43

US3062118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '11:53'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:50:43

US3062118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '3 Sep 2020 11:53'	System	04 Sep 2020 13:50:43

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:02:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '3 Sep 2020'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:51:07

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:02:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colton King (b) (4) (b) (4)	04 Sep 2020 13:51:07

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:51:07

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '11:56'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:51:07

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '3 Sep 2020 11:56'	System	04 Sep 2020 13:51:07

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:02:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colton King (b) (4) (b) (4)	04 Sep 2020 13:51:07

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	04 Sep 2020 13:51:07
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered empty.	Colton King (b) (4)	04 Sep 2020 13:51:07
	(b) (4)	

US3062118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered empty.	System	04 Sep 2020 13:51:07

US3062118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	04 Sep 2020 13:51:22

US3062118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '1'	System	04 Sep 2020 13:51:22

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:07:54', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '19d46994-fc3a-4062-bd37-206cccc6cf84'	System	03 Sep 2020 18:08:31
User entered 'Yes (Y)'	System	03 Sep 2020 18:08:31

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:08:03', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '19d46994-fc3a-4062-bd37-206cccc6cf84'	System	03 Sep 2020 18:08:31
User entered '97.9'	System	03 Sep 2020 18:08:31

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:08:14', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '19d46994-fc3a-4062-bd37-206cccc6cf84'	System	03 Sep 2020 18:08:31
User entered 'No (N)'	System	03 Sep 2020 18:08:31

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:08:25', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '19d46994-fc3a-4062-bd37-206cccc6cf84'	System	03 Sep 2020 18:08:31
User entered '03 Sep 2020 13:08'	System	03 Sep 2020 18:08:31

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 12:46'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 15:16'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:09:07', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4c159b35-1c09-4bd8-a36e-0ffcf5f59945'	System	04 Sep 2020 00:11:05
User entered 'Yes (Y)'	System	04 Sep 2020 00:11:05

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:10:48', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4c159b35-1c09-4bd8-a36e-0ffcf5f59945'	System	04 Sep 2020 00:11:05
User entered '98.6'	System	04 Sep 2020 00:11:05

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:10:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4c159b35-1c09-4bd8-a36e-0ffcf5f59945'	System	04 Sep 2020 00:11:05
User entered 'No (N)'	System	04 Sep 2020 00:11:05

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '4c159b35-1c09-4bd8-a36e-0ffcf5f59945'	System	04 Sep 2020 00:11:05
User entered '03 Sep 2020 19:11'	System	04 Sep 2020 00:11:05

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 16:11'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 2'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:07:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5c6af6f2-0d56-45fe-864f-7f0cd99f52ca'	System	05 Sep 2020 00:08:02
User entered 'Yes (Y)'	System	05 Sep 2020 00:08:02

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:07:50', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5c6af6f2-0d56-45fe-864f-7f0cd99f52ca'	System	05 Sep 2020 00:08:02
User entered '98.7'	System	05 Sep 2020 00:08:02

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:07:54', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5c6af6f2-0d56-45fe-864f-7f0cd99f52ca'	System	05 Sep 2020 00:08:02
User entered 'No (N)'	System	05 Sep 2020 00:08:02

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:07:59', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5c6af6f2-0d56-45fe-864f-7f0cd99f52ca'	System	05 Sep 2020 00:08:02
User entered '04 Sep 2020 19:07'	System	05 Sep 2020 00:08:02

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 3'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:22:13', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ce75c536-44ed-41cd-9c91-b4bbfb94a1ce'	System	06 Sep 2020 00:22:37
User entered 'Yes (Y)'	System	06 Sep 2020 00:22:37

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:22:24', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ce75c536-44ed-41cd-9c91-b4bbfb94a1ce'	System	06 Sep 2020 00:22:37
User entered '98.2'	System	06 Sep 2020 00:22:37

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:22:29', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ce75c536-44ed-41cd-9c91-b4bbfb94a1ce'	System	06 Sep 2020 00:22:37
User entered 'No (N)'	System	06 Sep 2020 00:22:37

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:22:35', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ce75c536-44ed-41cd-9c91-b4bbfb94a1ce'	System	06 Sep 2020 00:22:37
User entered '05 Sep 2020 19:22'	System	06 Sep 2020 00:22:37

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 4'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ca85f455-c0c0-4809-8359-9e450e5319c9'	System	07 Sep 2020 00:19:20
User entered 'Yes (Y)'	System	07 Sep 2020 00:19:20

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:06', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ca85f455-c0c0-4809-8359-9e450e5319c9'	System	07 Sep 2020 00:19:20
User entered '98.2'	System	07 Sep 2020 00:19:20

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:12', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ca85f455-c0c0-4809-8359-9e450e5319c9'	System	07 Sep 2020 00:19:20
User entered 'No (N)'	System	07 Sep 2020 00:19:20

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:16', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ca85f455-c0c0-4809-8359-9e450e5319c9'	System	07 Sep 2020 00:19:20
User entered '06 Sep 2020 19:19'	System	07 Sep 2020 00:19:20

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 5'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:43:55', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ad7067be-8508-4077-aa60-dd4984263a9a'	System	07 Sep 2020 23:44:15
User entered 'Yes (Y)'	System	07 Sep 2020 23:44:15

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:03', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ad7067be-8508-4077-aa60-dd4984263a9a'	System	07 Sep 2020 23:44:15
User entered '99.2'	System	07 Sep 2020 23:44:15

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:08', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ad7067be-8508-4077-aa60-dd4984263a9a'	System	07 Sep 2020 23:44:15
User entered 'No (N)'	System	07 Sep 2020 23:44:15

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:13', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ad7067be-8508-4077-aa60-dd4984263a9a'	System	07 Sep 2020 23:44:15
User entered '07 Sep 2020 18:44'	System	07 Sep 2020 23:44:15

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 6'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:12:11', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '04047741-a71c-4288-a8a1-43e9d92e698c'	System	09 Sep 2020 00:13:19
User entered 'Yes (Y)'	System	09 Sep 2020 00:13:19

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:12:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '04047741-a71c-4288-a8a1-43e9d92e698c'	System	09 Sep 2020 00:13:19
User entered '98.2'	System	09 Sep 2020 00:13:19

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:05', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '04047741-a71c-4288-a8a1-43e9d92e698c'	System	09 Sep 2020 00:13:19
User entered 'No (N)'	System	09 Sep 2020 00:13:19

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:16', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '04047741-a71c-4288-a8a1-43e9d92e698c'	System	09 Sep 2020 00:13:19
User entered '08 Sep 2020 19:13'	System	09 Sep 2020 00:13:19

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 7'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:01:20', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '141134ed-5562-4f52-bd2a-3f0ad072031b'	System	10 Sep 2020 00:01:41
User entered 'Yes (Y)'	System	10 Sep 2020 00:01:41

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:01:28', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '141134ed-5562-4f52-bd2a-3f0ad072031b'	System	10 Sep 2020 00:01:41
User entered '97.4'	System	10 Sep 2020 00:01:41

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:01:33', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '141134ed-5562-4f52-bd2a-3f0ad072031b'	System	10 Sep 2020 00:01:41
User entered 'No (N)'	System	10 Sep 2020 00:01:41

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:01:39', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '141134ed-5562-4f52-bd2a-3f0ad072031b'	System	10 Sep 2020 00:01:41
User entered '09 Sep 2020 19:01'	System	10 Sep 2020 00:01:41

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:09:23', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ef704106-f088-4e07-9567-e4c9e265eada'	System	03 Sep 2020 18:09:58
User entered 'None (1)'	System	03 Sep 2020 18:09:58

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:09:28', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ef704106-f088-4e07-9567-e4c9e265eada'	System	03 Sep 2020 18:09:58
User entered 'No (N)'	System	03 Sep 2020 18:09:58

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:09:32', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ef704106-f088-4e07-9567-e4c9e265eada'	System	03 Sep 2020 18:09:58
User entered 'No (N)'	System	03 Sep 2020 18:09:58

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:09:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ef704106-f088-4e07-9567-e4c9e265eada'	System	03 Sep 2020 18:09:58
User entered 'None (1)'	System	03 Sep 2020 18:09:58

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:09:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ef704106-f088-4e07-9567-e4c9e265eada'	System	03 Sep 2020 18:09:58
User entered '03 Sep 2020 13:09'	System	03 Sep 2020 18:09:58

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 12:46'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 15:16'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:14', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e1596385-88dc-4915-8579-c8ecbcb7fe79'	System	04 Sep 2020 00:11:42
User entered 'None (1)'	System	04 Sep 2020 00:11:42

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:18', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e1596385-88dc-4915-8579-c8ecbcb7fe79'	System	04 Sep 2020 00:11:42
User entered 'No (N)'	System	04 Sep 2020 00:11:42

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:23', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e1596385-88dc-4915-8579-c8ecbcb7fe79'	System	04 Sep 2020 00:11:42
User entered 'No (N)'	System	04 Sep 2020 00:11:42

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e1596385-88dc-4915-8579-c8ecbcb7fe79'	System	04 Sep 2020 00:11:42
User entered 'None (1)'	System	04 Sep 2020 00:11:42

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:37', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e1596385-88dc-4915-8579-c8ecbcb7fe79'	System	04 Sep 2020 00:11:42
User entered '03 Sep 2020 19:11'	System	04 Sep 2020 00:11:42

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 16:11'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 2'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:07', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '943a1df2-3eab-4e37-a1b2-50740fbfbb42'	System	05 Sep 2020 00:08:36
User entered 'None (1)'	System	05 Sep 2020 00:08:36

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:13', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '943a1df2-3eab-4e37-a1b2-50740fbfbb42'	System	05 Sep 2020 00:08:36
User entered 'No (N)'	System	05 Sep 2020 00:08:36

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:17', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '943a1df2-3eab-4e37-a1b2-50740fbfbb42'	System	05 Sep 2020 00:08:36
User entered 'No (N)'	System	05 Sep 2020 00:08:36

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:26', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '943a1df2-3eab-4e37-a1b2-50740fbfbb42'	System	05 Sep 2020 00:08:36
User entered 'None (1)'	System	05 Sep 2020 00:08:36

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:32', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '943a1df2-3eab-4e37-a1b2-50740fbfbb42'	System	05 Sep 2020 00:08:36
User entered '04 Sep 2020 19:08'	System	05 Sep 2020 00:08:36

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 3'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:22:48', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '625a2d53-2d81-4ed1-80ef-8badf1cb5e06'	System	06 Sep 2020 00:23:12
User entered 'None (1)'	System	06 Sep 2020 00:23:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:22:52', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '625a2d53-2d81-4ed1-80ef-8badf1cb5e06'	System	06 Sep 2020 00:23:12
User entered 'No (N)'	System	06 Sep 2020 00:23:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:22:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '625a2d53-2d81-4ed1-80ef-8badf1cb5e06'	System	06 Sep 2020 00:23:12
User entered 'No (N)'	System	06 Sep 2020 00:23:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:03', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '625a2d53-2d81-4ed1-80ef-8badf1cb5e06'	System	06 Sep 2020 00:23:12
User entered 'None (1)'	System	06 Sep 2020 00:23:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:09', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '625a2d53-2d81-4ed1-80ef-8badf1cb5e06'	System	06 Sep 2020 00:23:12
User entered '05 Sep 2020 19:23'	System	06 Sep 2020 00:23:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 4'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:24', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fd7319bb-7a72-4273-aacf-8d0b141fa6b2'	System	07 Sep 2020 00:19:45
User entered 'None (1)'	System	07 Sep 2020 00:19:45

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:28', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fd7319bb-7a72-4273-aacf-8d0b141fa6b2'	System	07 Sep 2020 00:19:45
User entered 'No (N)'	System	07 Sep 2020 00:19:45

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:33', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fd7319bb-7a72-4273-aacf-8d0b141fa6b2'	System	07 Sep 2020 00:19:45
User entered 'No (N)'	System	07 Sep 2020 00:19:45

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:37', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fd7319bb-7a72-4273-aacf-8d0b141fa6b2'	System	07 Sep 2020 00:19:45
User entered 'None (1)'	System	07 Sep 2020 00:19:45

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:41', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fd7319bb-7a72-4273-aacf-8d0b141fa6b2'	System	07 Sep 2020 00:19:45
User entered '06 Sep 2020 19:19'	System	07 Sep 2020 00:19:45

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 5'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:21', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e31e35a9-5504-449d-bcd9-d26b801dbccf'	System	07 Sep 2020 23:44:46
User entered 'None (1)'	System	07 Sep 2020 23:44:46

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:29', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e31e35a9-5504-449d-bcd9-d26b801dbccf'	System	07 Sep 2020 23:44:46
User entered 'No (N)'	System	07 Sep 2020 23:44:46

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:33', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e31e35a9-5504-449d-bcd9-d26b801dbccf'	System	07 Sep 2020 23:44:46
User entered 'No (N)'	System	07 Sep 2020 23:44:46

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e31e35a9-5504-449d-bcd9-d26b801dbccf'	System	07 Sep 2020 23:44:46
User entered 'None (1)'	System	07 Sep 2020 23:44:46

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:44', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e31e35a9-5504-449d-bcd9-d26b801dbccf'	System	07 Sep 2020 23:44:46
User entered '07 Sep 2020 18:44'	System	07 Sep 2020 23:44:46

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 6'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:21', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '51c639c8-8c5b-4650-a996-801ef897e5d0'	System	09 Sep 2020 00:13:37
User entered 'None (1)'	System	09 Sep 2020 00:13:37

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:24', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '51c639c8-8c5b-4650-a996-801ef897e5d0'	System	09 Sep 2020 00:13:37
User entered 'No (N)'	System	09 Sep 2020 00:13:37

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:27', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '51c639c8-8c5b-4650-a996-801ef897e5d0'	System	09 Sep 2020 00:13:37
User entered 'No (N)'	System	09 Sep 2020 00:13:37

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:29', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '51c639c8-8c5b-4650-a996-801ef897e5d0'	System	09 Sep 2020 00:13:37
User entered 'None (1)'	System	09 Sep 2020 00:13:37

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:33', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '51c639c8-8c5b-4650-a996-801ef897e5d0'	System	09 Sep 2020 00:13:37
User entered '08 Sep 2020 19:13'	System	09 Sep 2020 00:13:37

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 7'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:01:44', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e359bdfd-bb2d-4574-91d9-c7b5605784fe'	System	10 Sep 2020 00:02:14
User entered 'None (1)'	System	10 Sep 2020 00:02:14

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:01:49', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e359bdfd-bb2d-4574-91d9-c7b5605784fe'	System	10 Sep 2020 00:02:14
User entered 'No (N)'	System	10 Sep 2020 00:02:14

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:01:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e359bdfd-bb2d-4574-91d9-c7b5605784fe'	System	10 Sep 2020 00:02:14
User entered 'No (N)'	System	10 Sep 2020 00:02:14

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:03', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e359bdfd-bb2d-4574-91d9-c7b5605784fe'	System	10 Sep 2020 00:02:14
User entered 'None (1)'	System	10 Sep 2020 00:02:14

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:11', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e359bfdf-bb2d-4574-91d9-c7b5605784fe'	System	10 Sep 2020 00:02:14
User entered '09 Sep 2020 19:02'	System	10 Sep 2020 00:02:14

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:11:22', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0bff1adb-39cb-4027-a3bb-4fab9a951e70'	System	03 Sep 2020 18:12:44
User entered 'None (0)'	System	03 Sep 2020 18:12:44

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:11:27', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0bff1adb-39cb-4027-a3bb-4fab9a951e70'	System	03 Sep 2020 18:12:44
User entered 'None (0)'	System	03 Sep 2020 18:12:44

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:11:32', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0bffaadb-39cb-4027-a3bb-4fab9a951e70'	System	03 Sep 2020 18:12:44
User entered 'None (0)'	System	03 Sep 2020 18:12:44

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:11:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0bff1adb-39cb-4027-a3bb-4fab9a951e70'	System	03 Sep 2020 18:12:44
User entered 'None (0)'	System	03 Sep 2020 18:12:44

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:11:41', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0bff1adb-39cb-4027-a3bb-4fab9a951e70'	System	03 Sep 2020 18:12:44
User entered 'None (0)'	System	03 Sep 2020 18:12:44

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:11:46', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0bff1adb-39cb-4027-a3bb-4fab9a951e70'	System	03 Sep 2020 18:12:44
User entered 'None (0)'	System	03 Sep 2020 18:12:44

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:11:52', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0bff1adb-39cb-4027-a3bb-4fab9a951e70'	System	03 Sep 2020 18:12:44
User entered 'No (N)'	System	03 Sep 2020 18:12:44

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T13:12:39', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0bffaadb-39cb-4027-a3bb-4fab9a951e70'	System	03 Sep 2020 18:12:44
User entered '03 Sep 2020 13:12'	System	03 Sep 2020 18:12:44

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 12:46'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 15:16'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f49583a3-e65a-4f09-8c05-12833e3b6c9a'	System	04 Sep 2020 00:12:14
User entered 'None (0)'	System	04 Sep 2020 00:12:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:47', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f49583a3-e65a-4f09-8c05-12833e3b6c9a'	System	04 Sep 2020 00:12:14
User entered 'None (0)'	System	04 Sep 2020 00:12:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:50', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f49583a3-e65a-4f09-8c05-12833e3b6c9a'	System	04 Sep 2020 00:12:14
User entered 'None (0)'	System	04 Sep 2020 00:12:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f49583a3-e65a-4f09-8c05-12833e3b6c9a'	System	04 Sep 2020 00:12:14
User entered 'None (0)'	System	04 Sep 2020 00:12:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f49583a3-e65a-4f09-8c05-12833e3b6c9a'	System	04 Sep 2020 00:12:14
User entered 'None (0)'	System	04 Sep 2020 00:12:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:11:59', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f49583a3-e65a-4f09-8c05-12833e3b6c9a'	System	04 Sep 2020 00:12:14
User entered 'None (0)'	System	04 Sep 2020 00:12:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:12:03', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f49583a3-e65a-4f09-8c05-12833e3b6c9a'	System	04 Sep 2020 00:12:14
User entered 'No (N)'	System	04 Sep 2020 00:12:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-03T19:12:09', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f49583a3-e65a-4f09-8c05-12833e3b6c9a'	System	04 Sep 2020 00:12:14
User entered '03 Sep 2020 19:12'	System	04 Sep 2020 00:12:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '03 Sep 2020 16:11'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 2'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bd0dbe86-f226-4517-8826-eda70f0c644e'	System	05 Sep 2020 00:09:14
User entered 'None (0)'	System	05 Sep 2020 00:09:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:41', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bd0dbe86-f226-4517-8826-eda70f0c644e'	System	05 Sep 2020 00:09:14
User entered 'None (0)'	System	05 Sep 2020 00:09:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:44', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bd0dbe86-f226-4517-8826-eda70f0c644e'	System	05 Sep 2020 00:09:14
User entered 'None (0)'	System	05 Sep 2020 00:09:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:47', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bd0dbe86-f226-4517-8826-eda70f0c644e'	System	05 Sep 2020 00:09:14
User entered 'None (0)'	System	05 Sep 2020 00:09:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:50', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bd0dbe86-f226-4517-8826-eda70f0c644e'	System	05 Sep 2020 00:09:14
User entered 'None (0)'	System	05 Sep 2020 00:09:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:08:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bd0dbe86-f226-4517-8826-eda70f0c644e'	System	05 Sep 2020 00:09:14
User entered 'None (0)'	System	05 Sep 2020 00:09:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:09:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bd0dbe86-f226-4517-8826-eda70f0c644e'	System	05 Sep 2020 00:09:14
User entered 'No (N)'	System	05 Sep 2020 00:09:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-04T19:09:10', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bd0dbe86-f226-4517-8826-eda70f0c644e'	System	05 Sep 2020 00:09:14
User entered '04 Sep 2020 19:09'	System	05 Sep 2020 00:09:14

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 3'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:16', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5070f994-ee3f-481b-9786-7d400bb191ec'	System	06 Sep 2020 00:23:54
User entered 'None (0)'	System	06 Sep 2020 00:23:54

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:22', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5070f994-ee3f-481b-9786-7d400bb191ec'	System	06 Sep 2020 00:23:54
User entered 'None (0)'	System	06 Sep 2020 00:23:54

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:25', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5070f994-ee3f-481b-9786-7d400bb191ec'	System	06 Sep 2020 00:23:54
User entered 'None (0)'	System	06 Sep 2020 00:23:54

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:29', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5070f994-ee3f-481b-9786-7d400bb191ec'	System	06 Sep 2020 00:23:54
User entered 'None (0)'	System	06 Sep 2020 00:23:54

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:33', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5070f994-ee3f-481b-9786-7d400bb191ec'	System	06 Sep 2020 00:23:54
User entered 'None (0)'	System	06 Sep 2020 00:23:54

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:36', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5070f994-ee3f-481b-9786-7d400bb191ec'	System	06 Sep 2020 00:23:54
User entered 'None (0)'	System	06 Sep 2020 00:23:54

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5070f994-ee3f-481b-9786-7d400bb191ec'	System	06 Sep 2020 00:23:54
User entered 'No (N)'	System	06 Sep 2020 00:23:54

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-05T19:23:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5070f994-ee3f-481b-9786-7d400bb191ec'	System	06 Sep 2020 00:23:54
User entered '05 Sep 2020 19:23'	System	06 Sep 2020 00:23:54

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 4'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:47', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f1600050-c660-4dfc-a2e8-e25832ca11b1'	System	07 Sep 2020 00:20:15
User entered 'None (0)'	System	07 Sep 2020 00:20:15

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:50', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f1600050-c660-4dfc-a2e8-e25832ca11b1'	System	07 Sep 2020 00:20:15
User entered 'None (0)'	System	07 Sep 2020 00:20:15

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f1600050-c660-4dfc-a2e8-e25832ca11b1'	System	07 Sep 2020 00:20:15
User entered 'None (0)'	System	07 Sep 2020 00:20:15

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:55', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f1600050-c660-4dfc-a2e8-e25832ca11b1'	System	07 Sep 2020 00:20:15
User entered 'None (0)'	System	07 Sep 2020 00:20:15

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:19:59', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f1600050-c660-4dfc-a2e8-e25832ca11b1'	System	07 Sep 2020 00:20:15
User entered 'None (0)'	System	07 Sep 2020 00:20:15

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:20:02', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f1600050-c660-4dfc-a2e8-e25832ca11b1'	System	07 Sep 2020 00:20:15
User entered 'None (0)'	System	07 Sep 2020 00:20:15

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:20:06', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f1600050-c660-4dfc-a2e8-e25832ca11b1'	System	07 Sep 2020 00:20:15
User entered 'No (N)'	System	07 Sep 2020 00:20:15

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-06T19:20:11', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f1600050-c660-4dfc-a2e8-e25832ca11b1' User entered '06 Sep 2020 19:20'	System	07 Sep 2020 00:20:15
	System	07 Sep 2020 00:20:15

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 5'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:49', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f448e00a-8854-49ce-98dc-b7ec1f435c3d'	System	07 Sep 2020 23:45:23
User entered 'None (0)'	System	07 Sep 2020 23:45:23

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f448e00a-8854-49ce-98dc-b7ec1f435c3d'	System	07 Sep 2020 23:45:23
User entered 'None (0)'	System	07 Sep 2020 23:45:23

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:44:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f448e00a-8854-49ce-98dc-b7ec1f435c3d'	System	07 Sep 2020 23:45:23
User entered 'None (0)'	System	07 Sep 2020 23:45:23

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:45:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f448e00a-8854-49ce-98dc-b7ec1f435c3d'	System	07 Sep 2020 23:45:23
User entered 'None (0)'	System	07 Sep 2020 23:45:23

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:45:03', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f448e00a-8854-49ce-98dc-b7ec1f435c3d'	System	07 Sep 2020 23:45:23
User entered 'None (0)'	System	07 Sep 2020 23:45:23

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:45:07', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f448e00a-8854-49ce-98dc-b7ec1f435c3d'	System	07 Sep 2020 23:45:23
User entered 'None (0)'	System	07 Sep 2020 23:45:23

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:45:14', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f448e00a-8854-49ce-98dc-b7ec1f435c3d'	System	07 Sep 2020 23:45:23
User entered 'No (N)'	System	07 Sep 2020 23:45:23

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-07T18:45:21', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f448e00a-8854-49ce-98dc-b7ec1f435c3d'	System	07 Sep 2020 23:45:23
User entered '07 Sep 2020 18:45'	System	07 Sep 2020 23:45:23

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 6'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a4f41f47-4a06-405a-b930-49d92f8084d6'	System	09 Sep 2020 00:14:08
User entered 'None (0)'	System	09 Sep 2020 00:14:08

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:41', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a4f41f47-4a06-405a-b930-49d92f8084d6'	System	09 Sep 2020 00:14:08
User entered 'None (0)'	System	09 Sep 2020 00:14:08

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:44', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a4f41f47-4a06-405a-b930-49d92f8084d6'	System	09 Sep 2020 00:14:08
User entered 'None (0)'	System	09 Sep 2020 00:14:08

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:47', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a4f41f47-4a06-405a-b930-49d92f8084d6'	System	09 Sep 2020 00:14:08
User entered 'None (0)'	System	09 Sep 2020 00:14:08

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:50', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a4f41f47-4a06-405a-b930-49d92f8084d6'	System	09 Sep 2020 00:14:08
User entered 'None (0)'	System	09 Sep 2020 00:14:08

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a4f41f47-4a06-405a-b930-49d92f8084d6'	System	09 Sep 2020 00:14:08
User entered 'None (0)'	System	09 Sep 2020 00:14:08

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:13:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a4f41f47-4a06-405a-b930-49d92f8084d6'	System	09 Sep 2020 00:14:08
User entered 'No (N)'	System	09 Sep 2020 00:14:08

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-08T19:14:03', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'a4f41f47-4a06-405a-b930-49d92f8084d6'	System	09 Sep 2020 00:14:08
User entered '08 Sep 2020 19:14'	System	09 Sep 2020 00:14:08

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	03 Sep 2020 17:39:12
User entered 'Day 7'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:17', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '254546e8-13dd-4f10-933e-9bdf56c91601'	System	10 Sep 2020 00:02:47
User entered 'None (0)'	System	10 Sep 2020 00:02:47

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:21', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '254546e8-13dd-4f10-933e-9bdf56c91601'	System	10 Sep 2020 00:02:47
User entered 'None (0)'	System	10 Sep 2020 00:02:47

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:24', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '254546e8-13dd-4f10-933e-9bdf56c91601'	System	10 Sep 2020 00:02:47
User entered 'None (0)'	System	10 Sep 2020 00:02:47

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:27', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '254546e8-13dd-4f10-933e-9bdf56c91601'	System	10 Sep 2020 00:02:47
User entered 'None (0)'	System	10 Sep 2020 00:02:47

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '254546e8-13dd-4f10-933e-9bdf56c91601'	System	10 Sep 2020 00:02:47
User entered 'None (0)'	System	10 Sep 2020 00:02:47

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:34', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '254546e8-13dd-4f10-933e-9bdf56c91601'	System	10 Sep 2020 00:02:47
User entered 'None (0)'	System	10 Sep 2020 00:02:47

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '254546e8-13dd-4f10-933e-9bdf56c91601'	System	10 Sep 2020 00:02:47
User entered 'No (N)'	System	10 Sep 2020 00:02:47

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-09-09T19:02:44', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '254546e8-13dd-4f10-933e-9bdf56c91601'	System	10 Sep 2020 00:02:47
User entered '09 Sep 2020 19:02'	System	10 Sep 2020 00:02:47

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:39:12

US3062118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:02:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:39:12

US3062118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	11 Sep 2020 17:12:23

US3062118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '10 Sep 2020'	Colton King (b) (4)	11 Sep 2020 17:12:23
	(b) (4)	

US3062118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	11 Sep 2020 17:12:23
	(b) (4)	

US3062118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	11 Sep 2020 17:12:23

US3062118

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	11 Sep 2020 17:12:27

US3062118

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'I'	System	11 Sep 2020 17:12:27

US3062118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	17 Sep 2020 20:15:50

US3062118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '17 Sep 2020'	(b) (4) Colton King (b) (4)	17 Sep 2020 20:15:50

US3062118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	17 Sep 2020 20:15:50
	(b) (4)	

US3062118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Colton King (b) (4)	17 Sep 2020 20:15:50

US3062118

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	17 Sep 2020 20:15:42
	(b) (4)	

US3062118

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '1'	System	17 Sep 2020 20:15:42

US3062118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	25 Sep 2020 16:24:26
	(b) (4)	

US3062118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '24 Sep 2020'	Janna Martinez (b) (4)	25 Sep 2020 16:24:26

US3062118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	25 Sep 2020 16:24:26

US3062118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Janna Martinez (b) (4)	25 Sep 2020 16:24:26
	(b) (4)	

US3062118

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	25 Sep 2020 16:24:30
	(b) (4)	

US3062118

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'I'	System	25 Sep 2020 16:24:30

US3062118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	01 Oct 2020 16:43:46
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '01 Oct 2020'	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:43:46
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	01 Oct 2020 16:43:49
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Janna Martinez (b) (4)	01 Oct 2020 16:43:49
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	01 Oct 2020 16:43:46
User entered empty.	Janna Martinez (b) (4)	01 Oct 2020 16:43:46
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'VISIT3'	System	01 Oct 2020 16:43:46

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '01 Oct 2020'	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '11:14'	Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '01 Oct 2020 11:14'	System	01 Oct 2020 16:44:22

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '99.3' F	Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered '60'	Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'bpm'	System	01 Oct 2020 16:44:22

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '14'	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:44:22

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'breaths/min'	System	01 Oct 2020 16:44:22

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '100'	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	01 Oct 2020 16:44:22

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '62'	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:44:22
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered 'mmHg'	System	01 Oct 2020 16:44:22

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56

US3062118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56

US3062118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	01 Oct 2020 16:44:37
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered empty.	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:44:37
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered 'Yes (Y)'	Janna Martinez (b) (4)	01 Oct 2020 16:44:47

US3062118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '01 Oct 2020'	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:44:47
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
User entered '11:24'	(b) (4) Janna Martinez (b) (4)	01 Oct 2020 16:44:47
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '01 Oct 2020 11:24'	System	01 Oct 2020 16:44:47

US3062118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:27:31
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	01 Oct 2020 16:43:30
	(b) (4)	

US3062118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '1'	System	01 Oct 2020 16:43:30

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 64'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-09T10:58:18', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '780818dd-f7d3-4eec-bc74-5456830e299f'	System	09 Oct 2020 15:58:59
User entered 'No (N)'	System	09 Oct 2020 15:58:59

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-09T10:58:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '780818dd-f7d3-4eec-bc74-5456830e299f'	System	09 Oct 2020 15:58:59
User entered 'No (N)'	System	09 Oct 2020 15:58:59

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-09T10:58:57', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '780818dd-f7d3-4eec-bc74-5456830e299f' User entered '09 Oct 2020 10:58:57'	System	09 Oct 2020 15:58:59
	System	09 Oct 2020 15:58:59

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 71'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-16T11:26:54', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0c8c2fa7-a37c-4016-8c0f-7694171ad038'	System	16 Oct 2020 16:27:28
User entered 'No (N)'	System	16 Oct 2020 16:27:28

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-16T11:27:08', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0c8c2fa7-a37c-4016-8c0f-7694171ad038'	System	16 Oct 2020 16:27:28
User entered 'No (N)'	System	16 Oct 2020 16:27:28

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-16T11:27:26', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '0c8c2fa7-a37c-4016-8c0f-7694171ad038'	System	16 Oct 2020 16:27:28
User entered '16 Oct 2020 11:27:26'	System	16 Oct 2020 16:27:28

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 78'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-23T17:13:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '438d40f2-5ac4-477e-b4c2-9a54a6691ee8'	System	23 Oct 2020 22:14:18
User entered 'No (N)'	System	23 Oct 2020 22:14:18

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-23T17:13:53', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '438d40f2-5ac4-477e-b4c2-9a54a6691ee8'	System	23 Oct 2020 22:14:18
User entered 'No (N)'	System	23 Oct 2020 22:14:18

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-10-23T17:14:13', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '438d40f2-5ac4-477e-b4c2-9a54a6691ee8' User entered '23 Oct 2020 17:14:13'	System	23 Oct 2020 22:14:18
	System	23 Oct 2020 22:14:18

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 92'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-03T07:28:49', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '07b31b47-55e4-4eb8-ad54-b63275d698b4'	System	03 Nov 2020 13:29:14
User entered 'No (N)'	System	03 Nov 2020 13:29:14

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-03T07:29:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '07b31b47-55e4-4eb8-ad54-b63275d698b4'	System	03 Nov 2020 13:29:14
User entered 'No (N)'	System	03 Nov 2020 13:29:14

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-03T07:29:11', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '07b31b47-55e4-4eb8-ad54-b63275d698b4'	System	03 Nov 2020 13:29:14
User entered '03 Nov 2020 07:29:11'	System	03 Nov 2020 13:29:14

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 99'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-11T11:22:33', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '747133c2-89f9-40c9-9a72-82d60d2e6f87'	System	11 Nov 2020 17:22:58
User entered 'No (N)'	System	11 Nov 2020 17:22:58

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-11T11:22:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '747133c2-89f9-40c9-9a72-82d60d2e6f87'	System	11 Nov 2020 17:22:58
User entered 'No (N)'	System	11 Nov 2020 17:22:58

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-11T11:22:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '747133c2-89f9-40c9-9a72-82d60d2e6f87'	System	11 Nov 2020 17:22:58
User entered '11 Nov 2020 11:22:51'	System	11 Nov 2020 17:22:58

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered 'Day 106'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-17T07:12:29', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '45765b23-668f-4dc4-b3db-ee2e80f388f5'	System	17 Nov 2020 13:12:56
User entered 'No (N)'	System	17 Nov 2020 13:12:56

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-17T07:12:37', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '45765b23-668f-4dc4-b3db-ee2e80f388f5'	System	17 Nov 2020 13:12:56
User entered 'No (N)'	System	17 Nov 2020 13:12:56

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-17T07:12:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '45765b23-668f-4dc4-b3db-ee2e80f388f5'	System	17 Nov 2020 13:12:56
User entered '17 Nov 2020 07:12:51'	System	17 Nov 2020 13:12:56

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 17:55:41

US3062118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:57:53
Data entry locked.	System	06 Aug 2020 17:55:41
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 17:55:41

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2020-11-24T11:43:02', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '346993e9-ed5d-4790-8e74-de9143f3db38'	System	24 Nov 2020 17:43:19
User entered 'No (N)'	System	24 Nov 2020 17:43:19

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2020-11-24T11:43:10', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '346993e9-ed5d-4790-8e74-de9143f3db38'	System	24 Nov 2020 17:43:19
User entered 'No (N)'	System	24 Nov 2020 17:43:19

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-11-24T11:43:17', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '346993e9-ed5d-4790-8e74-de9143f3db38'	System	24 Nov 2020 17:43:19
User entered '24 Nov 2020 11:43:17'	System	24 Nov 2020 17:43:19

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2020-12-02T16:51:08', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e0de3f17-2251-42e3-a1ea-f66c221bf4bb'	System	02 Dec 2020 22:51:29
User entered 'No (N)'	System	02 Dec 2020 22:51:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2020-12-02T16:51:18', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e0de3f17-2251-42e3-a1ea-f66c221bf4bb'	System	02 Dec 2020 22:51:29
User entered 'No (N)'	System	02 Dec 2020 22:51:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-12-02T16:51:26', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e0de3f17-2251-42e3-a1ea-f66c221bf4bb'	System	02 Dec 2020 22:51:29
User entered '02 Dec 2020 16:51:26'	System	02 Dec 2020 22:51:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2020-12-05T11:20:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ecae21aa-2f7f-4241-863c-6738d5029c6e'	System	05 Dec 2020 17:20:54
User entered 'No (N)'	System	05 Dec 2020 17:20:54

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2020-12-05T11:20:47', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ecae21aa-2f7f-4241-863c-6738d5029c6e'	System	05 Dec 2020 17:20:54
User entered 'No (N)'	System	05 Dec 2020 17:20:54

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-12-05T11:20:52', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'ecae21aa-2f7f-4241-863c-6738d5029c6e'	System	05 Dec 2020 17:20:54
User entered '05 Dec 2020 11:20:52'	System	05 Dec 2020 17:20:54

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2020-12-16T11:43:31', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fab0eb9e-f48a-4bb8-973a-56db29e1fbb9'	System	16 Dec 2020 17:43:51
User entered 'No (N)'	System	16 Dec 2020 17:43:51

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2020-12-16T11:43:42', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fab0eb9e-f48a-4bb8-973a-56db29e1fbb9'	System	16 Dec 2020 17:43:51
User entered 'No (N)'	System	16 Dec 2020 17:43:51

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-12-16T11:43:47', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fab0eb9e-f48a-4bb8-973a-56db29e1fbb9' User entered '16 Dec 2020 11:43:47'	System	16 Dec 2020 17:43:51
	System	16 Dec 2020 17:43:51

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2020-12-19T11:12:48', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '42c362c8-34ee-427e-97a4-500561c183cf' User entered 'No (N)'	System	19 Dec 2020 17:13:12
	System	19 Dec 2020 17:13:12

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2020-12-19T11:13:02', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '42c362c8-34ee-427e-97a4-500561c183cf'	System	19 Dec 2020 17:13:12
User entered 'No (N)'	System	19 Dec 2020 17:13:12

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-12-19T11:13:08', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '42c362c8-34ee-427e-97a4-500561c183cf' User entered '19 Dec 2020 11:13:08'	System	19 Dec 2020 17:13:12
	System	19 Dec 2020 17:13:12

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2020-12-28T11:37:32', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bbaac14c-e286-445d-95b2-770d159bafef'	System	28 Dec 2020 17:37:49
User entered 'No (N)'	System	28 Dec 2020 17:37:49

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2020-12-28T11:37:39', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bbaac14c-e286-445d-95b2-770d159bafec'	System	28 Dec 2020 17:37:49
User entered 'No (N)'	System	28 Dec 2020 17:37:49

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2020-12-28T11:37:45', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'bbaac14c-e286-445d-95b2-770d159bafef'	System	28 Dec 2020 17:37:49
User entered '28 Dec 2020 11:37:45'	System	28 Dec 2020 17:37:49

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-01-04T16:51:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '93aec79d-2191-4f31-b319-78edd0642080'	System	04 Jan 2021 22:51:13
User entered 'No (N)'	System	04 Jan 2021 22:51:13

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-01-04T16:51:06', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '93aec79d-2191-4f31-b319-78edd0642080'	System	04 Jan 2021 22:51:13
User entered 'No (N)'	System	04 Jan 2021 22:51:13

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-01-04T16:51:11', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '93aec79d-2191-4f31-b319-78edd0642080'	System	04 Jan 2021 22:51:13
User entered '04 Jan 2021 16:51:11'	System	04 Jan 2021 22:51:13

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-01-11T17:43:18', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '46076d19-8dea-4d32-9fe3-980d5d659ab9'	System	11 Jan 2021 23:43:30
User entered 'No (N)'	System	11 Jan 2021 23:43:30

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-01-11T17:43:23', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '46076d19-8dea-4d32-9fe3-980d5d659ab9'	System	11 Jan 2021 23:43:30
User entered 'No (N)'	System	11 Jan 2021 23:43:30

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-01-11T17:43:28', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '46076d19-8dea-4d32-9fe3-980d5d659ab9'	System	11 Jan 2021 23:43:30
User entered '11 Jan 2021 17:43:28'	System	11 Jan 2021 23:43:30

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-01-16T08:37:15', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '2b4821aa-8031-4156-900c-2d5cff8f08f6'	System	16 Jan 2021 14:37:29
User entered 'No (N)'	System	16 Jan 2021 14:37:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-01-16T08:37:21', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '2b4821aa-8031-4156-900c-2d5cff8f08f6'	System	16 Jan 2021 14:37:29
User entered 'No (N)'	System	16 Jan 2021 14:37:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-01-16T08:37:24', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '2b4821aa-8031-4156-900c-2d5cff8f08f6' User entered '16 Jan 2021 08:37:24'	System	16 Jan 2021 14:37:29
	System	16 Jan 2021 14:37:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 (24e88297f54107fe)', Time: '2021-01-23T05:18:54', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '78f4b313-74e7-45b0-a166-b3c9a3eb7427'	System	23 Jan 2021 11:19:08
User entered 'No (N)'	System	23 Jan 2021 11:19:08

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-01-23T05:18:59', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '78f4b313-74e7-45b0-a166-b3c9a3eb7427'	System	23 Jan 2021 11:19:08
User entered 'No (N)'	System	23 Jan 2021 11:19:08

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-01-23T05:19:04', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '78f4b313-74e7-45b0-a166-b3c9a3eb7427'	System	23 Jan 2021 11:19:08
User entered '23 Jan 2021 05:19:04'	System	23 Jan 2021 11:19:08

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

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 (24e88297f54107fe)', Time: '2021-01-31T17:03:31', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5e87e5a2-08e6-4e19-b292-168209e1ade4'	System	31 Jan 2021 23:06:52
User entered 'No (N)'	System	31 Jan 2021 23:06:52

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-01-31T17:03:40', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5e87e5a2-08e6-4e19-b292-168209e1ade4'	System	31 Jan 2021 23:06:52
User entered 'No (N)'	System	31 Jan 2021 23:06:52

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-01-31T17:03:46', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '5e87e5a2-08e6-4e19-b292-168209e1ade4' User entered '31 Jan 2021 17:03:46'	System	31 Jan 2021 23:06:52
	System	31 Jan 2021 23:06:52

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-02-06T05:43:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'db447a76-d59b-4a8a-8a7d-a7bb13ae11f6'	System	06 Feb 2021 11:43:48
User entered 'No (N)'	System	06 Feb 2021 11:43:48

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-02-06T05:43:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'db447a76-d59b-4a8a-8a7d-a7bb13ae11f6'	System	06 Feb 2021 11:43:48
User entered 'No (N)'	System	06 Feb 2021 11:43:48

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-02-06T05:43:45', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'db447a76-d59b-4a8a-8a7d-a7bb13ae11f6'	System	06 Feb 2021 11:43:48
User entered '06 Feb 2021 05:43:45'	System	06 Feb 2021 11:43:48

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-02-15T11:01:39', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e8e16bc0-8f6b-4039-ad6e-134a9dd71719'	System	15 Feb 2021 17:08:13
User entered 'No (N)'	System	15 Feb 2021 17:08:13

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-02-15T11:01:44', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e8e16bc0-8f6b-4039-ad6e-134a9dd71719'	System	15 Feb 2021 17:08:13
User entered 'No (N)'	System	15 Feb 2021 17:08:13

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-02-15T11:01:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'e8e16bc0-8f6b-4039-ad6e-134a9dd71719'	System	15 Feb 2021 17:08:13
User entered '15 Feb 2021 11:01:51'	System	15 Feb 2021 17:08:13

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-02-21T20:40:35', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '1fced150-4095-40e9-9f08-9e50b169a473'	System	22 Feb 2021 02:40:54
User entered 'No (N)'	System	22 Feb 2021 02:40:54

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-02-21T20:40:43', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '1fced150-4095-40e9-9f08-9e50b169a473'	System	22 Feb 2021 02:40:54
User entered 'No (N)'	System	22 Feb 2021 02:40:54

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-02-21T20:40:51', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '1fced150-4095-40e9-9f08-9e50b169a473'	System	22 Feb 2021 02:40:54
User entered '21 Feb 2021 20:40:51'	System	22 Feb 2021 02:40:54

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-02-27T06:46:28', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fa832e33-19b2-435e-a65a-ba8660bca657'	System	27 Feb 2021 12:46:49
User entered 'No (N)'	System	27 Feb 2021 12:46:49

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-02-27T06:46:35', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fa832e33-19b2-435e-a65a-ba8660bca657'	System	27 Feb 2021 12:46:49
User entered 'No (N)'	System	27 Feb 2021 12:46:49

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-02-27T06:46:47', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'fa832e33-19b2-435e-a65a-ba8660bca657'	System	27 Feb 2021 12:46:49
User entered '27 Feb 2021 06:46:47'	System	27 Feb 2021 12:46:49

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-03-06T05:23:34', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '74967454-c04f-46ca-bba5-a78f6ab21e41'	System	06 Mar 2021 11:23:46
User entered 'No (N)'	System	06 Mar 2021 11:23:46

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-03-06T05:23:39', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '74967454-c04f-46ca-bba5-a78f6ab21e41'	System	06 Mar 2021 11:23:46
User entered 'No (N)'	System	06 Mar 2021 11:23:46

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-03-06T05:23:44', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '74967454-c04f-46ca-bba5-a78f6ab21e41'	System	06 Mar 2021 11:23:46
User entered '06 Mar 2021 05:23:44'	System	06 Mar 2021 11:23:46

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-03-15T13:31:05', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'dd76fed5-8f65-40ff-9d5f-5015c708632a'	System	15 Mar 2021 18:31:29
User entered 'No (N)'	System	15 Mar 2021 18:31:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-03-15T13:31:22', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'dd76fed5-8f65-40ff-9d5f-5015c708632a'	System	15 Mar 2021 18:31:29
User entered 'No (N)'	System	15 Mar 2021 18:31:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-03-15T13:31:28', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'dd76fed5-8f65-40ff-9d5f-5015c708632a'	System	15 Mar 2021 18:31:29
User entered '15 Mar 2021 13:31:28'	System	15 Mar 2021 18:31:29

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-03-22T12:49:24', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'eb597144-46cb-470e-aa55-62aeb12bfd12'	System	22 Mar 2021 17:49:37
User entered 'No (N)'	System	22 Mar 2021 17:49:37

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-03-22T12:49:30', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'eb597144-46cb-470e-aa55-62aeb12bfd12'	System	22 Mar 2021 17:49:37
User entered 'No (N)'	System	22 Mar 2021 17:49:37

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-03-22T12:49:34', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'eb597144-46cb-470e-aa55-62aeb12bfd12'	System	22 Mar 2021 17:49:37
User entered '22 Mar 2021 12:49:34'	System	22 Mar 2021 17:49:37

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-03-27T06:47:33', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'edc8c37d-5e73-4817-95cd-35885e801e87'	System	27 Mar 2021 11:47:50
User entered 'No (N)'	System	27 Mar 2021 11:47:50

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-03-27T06:47:38', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'edc8c37d-5e73-4817-95cd-35885e801e87'	System	27 Mar 2021 11:47:50
User entered 'No (N)'	System	27 Mar 2021 11:47:50

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-03-27T06:47:42', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'edc8c37d-5e73-4817-95cd-35885e801e87' User entered '27 Mar 2021 06:47:42'	System	27 Mar 2021 11:47:50
	System	27 Mar 2021 11:47:50

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-04-05T09:08:10-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '33490177-37cb-43b9-96d4-70475bc9d48a'	System	05 Apr 2021 14:08:30
User entered 'No (N)'	System	05 Apr 2021 14:08:30

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-04-05T09:08:19-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '33490177-37cb-43b9-96d4-70475bc9d48a'	System	05 Apr 2021 14:08:30
User entered 'No (N)'	System	05 Apr 2021 14:08:30

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-04-05T09:08:25-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '33490177-37cb-43b9-96d4-70475bc9d48a'	System	05 Apr 2021 14:08:30
User entered '05 Apr 2021 09:08:25'	System	05 Apr 2021 14:08:30

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-04-10T07:54:08-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7a4c0848-2b98-4fa3-85cb-0d17060e520f' User entered 'No (N)'	System	10 Apr 2021 12:54:28
	System	10 Apr 2021 12:54:28

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-04-10T07:54:15-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7a4c0848-2b98-4fa3-85cb-0d17060e520f' User entered 'No (N)'	System	10 Apr 2021 12:54:28
	System	10 Apr 2021 12:54:28

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-04-10T07:54:22-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '7a4c0848-2b98-4fa3-85cb-0d17060e520f' User entered '10 Apr 2021 07:54:22'	System	10 Apr 2021 12:54:28
	System	10 Apr 2021 12:54:28

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-04-17T07:47:31-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '3a36b4b0-1051-4846-a2b0-42843ff319dc'	System	17 Apr 2021 12:47:47
User entered 'No (N)'	System	17 Apr 2021 12:47:47

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-04-17T07:47:37-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '3a36b4b0-1051-4846-a2b0-42843ff319dc'	System	17 Apr 2021 12:47:47
User entered 'No (N)'	System	17 Apr 2021 12:47:47

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-04-17T07:47:43-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '3a36b4b0-1051-4846-a2b0-42843ff319dc'	System	17 Apr 2021 12:47:47
User entered '17 Apr 2021 07:47:43'	System	17 Apr 2021 12:47:47

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-04-26T11:32:36-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f583195c-f9a6-49fd-b392-7459337c53e7'	System	26 Apr 2021 16:32:46
User entered 'No (N)'	System	26 Apr 2021 16:32:46

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-04-26T11:32:40-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f583195c-f9a6-49fd-b392-7459337c53e7'	System	26 Apr 2021 16:32:46
User entered 'No (N)'	System	26 Apr 2021 16:32:46

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-04-26T11:32:44-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'f583195c-f9a6-49fd-b392-7459337c53e7'	System	26 Apr 2021 16:32:46
User entered '26 Apr 2021 11:32:44'	System	26 Apr 2021 16:32:46

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[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 (24e88297f54107fe)', Time: '2021-05-03T10:13:17-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'aeb039a7-f19e-47e9-8f85-2f59aeaca8e8'	System	03 May 2021 15:13:51
User entered 'No (N)'	System	03 May 2021 15:13:51

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

Have you been exposed to someone with 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 (24e88297f54107fe)', Time: '2021-05-03T10:13:23-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'aeb039a7-f19e-47e9-8f85-2f59aeaca8e8'	System	03 May 2021 15:13:51
User entered 'No (N)'	System	03 May 2021 15:13:51

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-05-03T10:13:27-05:00', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: 'aeb039a7-f19e-47e9-8f85-2f59aeaca8e8'	System	03 May 2021 15:13:51
User entered '03 May 2021 10:13:27'	System	03 May 2021 15:13:51

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:43:26

US3062118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:02:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:26
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:43:26

US3062118

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:02:24

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 22:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-02-27T06:46:56', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '2f19ea3a-00be-44ca-a850-e612d65085a9'	System	27 Feb 2021 12:47:12
User entered 'No (N)'	System	27 Feb 2021 12:47:12

US3062118

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:02:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24e88297f54107fe)', Time: '2021-02-27T06:47:09', User OID: 'PatientReportedOutcome (US3062118)', ODM File OID: '2f19ea3a-00be-44ca-a850-e612d65085a9'	System	27 Feb 2021 12:47:12
User entered '27 Feb 2021 06:47:09'	System	27 Feb 2021 12:47:12

US3062118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
User entered 'Yes (Y)'	(b) (4) Justin Phillips (b) (4)	27 Oct 2020 21:21:58
	(b) (4)	

US3062118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
User entered '27 Oct 2020'	(b) (4) Justin Phillips (b) (4)	27 Oct 2020 21:21:58
	(b) (4)	

US3062118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Justin Phillips (b) (4)	27 Oct 2020 21:21:58
	(b) (4)	

US3062118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
	(b) (4)	
User entered empty.	Justin Phillips (b) (4)	27 Oct 2020 21:21:58
	(b) (4)	

US3062118

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
User entered 'Yes (Y)'	(b) (4) Justin Phillips (b) (4)	27 Oct 2020 21:22:06
	(b) (4)	

US3062118

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 13:02:56
User entered '1'	System	27 Oct 2020 21:22:06

US3062118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Riley King (b) (4)	30 Nov 2020 23:58:11

US3062118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '30 Nov 2020'	Riley King (b) (4)	30 Nov 2020 23:58:11

US3062118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Riley King (b) (4) (b) (4)	30 Nov 2020 23:58:11

US3062118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Riley King (b) (4)	30 Nov 2020 23:58:11
	(b) (4)	

US3062118

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Riley King (b) (4)	30 Nov 2020 23:58:14

US3062118

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered 'I'	System	30 Nov 2020 23:58:14

US3062118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Riley King (b) (4)	30 Dec 2020 16:57:12

US3062118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '30 Dec 2020'	Riley King (b) (4)	30 Dec 2020 16:57:12

US3062118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	30 Dec 2020 16:57:12

US3062118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered empty.	(b) (4) Riley King (b) (4)	30 Dec 2020 16:57:12

US3062118

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Riley King (b) (4)	30 Dec 2020 16:57:17

US3062118

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered 'I'	System	30 Dec 2020 16:57:17

US3062118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 16:16:46

US3062118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '3 Feb 2021'	Colton King (b) (4)	04 Feb 2021 16:16:46

US3062118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	04 Feb 2021 16:16:46

US3062118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered empty.	(b) (4) Colton King (b) (4)	04 Feb 2021 16:16:46

US3062118

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 16:16:51

US3062118

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered '1'	System	04 Feb 2021 16:16:51

US3062118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 06:40:35
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'data corrected' (Site from DM).	Janna Martinez (b) (4)	31 Mar 2021 19:08:09
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:29:29
User entered 'Yes (Y)'	Colton King (b) (4)	05 Mar 2021 14:41:52

US3062118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '3 Mar 2021'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:52

US3062118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[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 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Clinic (Clinic)'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:52

US3062118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered 'VISIT4'	System	05 Mar 2021 14:41:52

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Janna Martinez (b) (4)	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '03 Mar 2021'	Janna Martinez (b) (4)	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '10:13'	Janna Martinez (b) (4)	31 Mar 2021 19:09:00
	(b) (4)	

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered '03 Mar 2021 10:13'	System	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '98.3' F	Janna Martinez (b) (4)	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered empty.	Janna Martinez (b) (4)	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '66'	(b) (4) Janna Martinez (b) (4)	31 Mar 2021 19:09:00
	(b) (4)	

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered 'bpm'	System	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '14'	Janna Martinez (b) (4)	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered 'breaths/min'	System	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '113'	Janna Martinez (b) (4)	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered 'mmHg'	System	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '63'	Janna Martinez (b) (4)	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered 'mmHg'	System	31 Mar 2021 19:09:00

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03

US3062118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03

US3062118

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:22
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:52:45
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:42:39
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	20 Apr 2021 14:48:20
Signature has been broken.	marissa Mueller (b) (4)	20 Apr 2021 14:48:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	20 Apr 2021 14:48:01
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 10:15:25
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:15:25
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:32:51

US3062118

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' answered with 'Visit 4- only symptom directed is required OL Day 29- investigator is required to assess lymph nodes and injection arm ie part of a physical. If visit 4 did not require lab but OI D29 did, we would document as such as each tab is visit/protocol derived. ' (Site from DM).	marissa Mueller (b) (4) (b) (4)	02 Apr 2021 13:32:40
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:35:18
User closed query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:35:18
Query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' answered with 'per protocol, px not required at this visit. This would be the same if immunogenicity was drawn at one and not the other per protocol. Correct as entered' (Site from DM).	marissa Mueller (b) (4) (b) (4)	31 Mar 2021 15:02:03
User opened query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:54:53

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:54:53
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'data correct as entered as Physical is not required for visit 4 but is required for OL-D29' (Site from DM).	Janna Martinez (b) (4)	30 Mar 2021 19:03:04
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:29:49
User entered 'No (N)'	Colton King (b) (4)	05 Mar 2021 14:42:27

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:13:22
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:52:45
Signature has been broken.	(b) (4) marissa Mueller (b) (4)	20 Apr 2021 14:48:01
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	20 Apr 2021 14:48:01
User signature succeeded.	(b) (4) Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered empty.	(b) (4) Colton King (b) (4)	05 Mar 2021 14:42:27
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Colton King (b) (4)	05 Mar 2021 14:42:38

US3062118

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '3 Mar 2021'	Colton King (b) (4)	05 Mar 2021 14:42:38

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '10:20'	Colton King (b) (4)	05 Mar 2021 14:42:38

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered '3 Mar 2021 10:20'	System	05 Mar 2021 14:42:38

US3062118

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Colton King (b) (4)	05 Mar 2021 14:42:43

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:27:03
User entered '1'	System	05 Mar 2021 14:42:43

US3062118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Colton King (b) (4)	30 Mar 2021 14:41:38

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '29 Mar 2021'	(b) (4) Colton King (b) (4)	30 Mar 2021 14:41:38

US3062118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	30 Mar 2021 14:41:38

US3062118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	30 Mar 2021 14:41:38
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	30 Mar 2021 14:41:45

US3062118

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:50
User entered 'I'	System	30 Mar 2021 14:41:45

US3062118

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

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4)	01 Feb 2021 22:45:34

US3062118

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

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '30 Jan 2021'	Sherry Henning (b) (4)	01 Feb 2021 22:45:34
	(b) (4)	

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

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[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 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Clinic (Clinic)'	(b) (4) Sherry Henning (b) (4)	01 Feb 2021 22:45:34

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

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 22:45:34

US3062118

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '30 Jan 2021'	Sherry Henning (b) (4)	01 Feb 2021 22:49:32
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '0'	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 15:02:08
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:08:30

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4)	01 Feb 2021 22:49:32

US3062118

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 15:02:08
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:08:30

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '30 Jan 2021'	Sherry Henning (b) (4)	01 Feb 2021 22:49:32
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Placebo (Placebo)'	Sherry Henning (b) (4)	01 Feb 2021 22:49:32
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Placebo (Placebo)'	Sherry Henning (b) (4)	01 Feb 2021 22:49:32
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Placebo (Placebo)'	(b) (4) Sherry Henning (b) (4)	01 Feb 2021 22:49:32

US3062118

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Feb 2021 22:49:32
	(b) (4)	

US3062118

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '1'	System	01 Feb 2021 22:49:32

US3062118

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

Form: Unblinding

Generated On: 09 Jun 2021 15:02:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '1'	System	01 Feb 2021 22:49:32

US3062118

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '167.0' cm	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '75.9' kg	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '27.21503'	System	01 Feb 2021 22:51:39
DataPoint set to visible.	System	01 Feb 2021 22:49:32

US3062118

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '167.0' cm	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

US3062118

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '75.9' kg	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '27.21503'	System	01 Feb 2021 22:51:39
DataPoint set to visible.	System	01 Feb 2021 22:49:32

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry Henning (b) (4) (b) (4)	01 Feb 2021 22:51:39

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '30 Jan 2021'	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '13:02'	(b) (4) Sherry Henning (b) (4)	01 Feb 2021 22:51:39

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '30 Jan 2021 13:02'	System	01 Feb 2021 22:51:39

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '97.2' F	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered empty.	(b) (4) Sherry Henning (b) (4)	01 Feb 2021 22:51:39

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '65'	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'bpm'	System	01 Feb 2021 22:51:39

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '16'	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'breaths/min'	System	01 Feb 2021 22:51:39

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '100'	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mmHg'	System	01 Feb 2021 22:51:39

US3062118

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
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).	(b) (4), (b) (6)	02 Feb 2021 04:16:03
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 with 'NCS per PI' (Site from System).	Sherry Henning (b) (4)	01 Feb 2021 22:52:01
	(b) (4)	
User opened query 'Diastolic Blood Pressure reported System 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).		01 Feb 2021 22:51:39
User entered '59'	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mmHg'	System	01 Feb 2021 22:51:39

US3062118

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '167.0' cm	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '75.9' kg	Sherry Henning (b) (4)	01 Feb 2021 22:51:39
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:02:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '27.21503'	System	01 Feb 2021 22:51:39
DataPoint set to visible.	System	01 Feb 2021 22:49:32

US3062118

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry Henning (b) (4) (b) (4)	01 Feb 2021 22:52:52

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '30 Jan 2021'	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '14:11'	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '30 Jan 2021 14:11'	System	01 Feb 2021 22:52:52

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '97.9' F	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '58'	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'bpm'	System	01 Feb 2021 22:52:52

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '14'	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'breaths/min'	System	01 Feb 2021 22:52:52

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '111'	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mmHg'	System	01 Feb 2021 22:52:52

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '69'	Sherry Henning (b) (4)	01 Feb 2021 22:52:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mmHg'	System	01 Feb 2021 22:52:52

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Feb 2021 22:53:14
	(b) (4)	

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '30 Jan 2021'	Sherry Henning (b) (4)	01 Feb 2021 22:53:14
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Feb 2021 22:53:41
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	01 Feb 2021 22:53:41
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

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 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered empty.	Sherry Henning (b) (4)	01 Feb 2021 22:53:41

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mRNA-1273'	System	01 Feb 2021 22:53:41
DataPoint set to visible.	System	01 Feb 2021 22:49:32

US3062118

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '30 Jan 2021'	Sherry Henning (b) (4)	01 Feb 2021 22:53:41
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '13:38'	Sherry Henning (b) (4)	01 Feb 2021 22:53:41
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '30 Jan 2021 13:38'	System	01 Feb 2021 22:53:41

US3062118

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4)	01 Feb 2021 22:53:41
	(b) (4)	

US3062118

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'ONCE'	System	01 Feb 2021 22:53:41

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

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 22:53:41

US3062118

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Feb 2021 22:54:17
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '30 Jan 2021'	Sherry Henning (b) (4)	01 Feb 2021 22:54:17
	(b) (4)	

US3062118

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '13:05'	Sherry Henning (b) (4)	01 Feb 2021 22:54:17
	(b) (4)	

US3062118

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '30 Jan 2021 13:05'	System	01 Feb 2021 22:54:17

US3062118

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Feb 2021 22:54:31
	(b) (4)	

US3062118

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:02:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '30 Jan 2021'	(b) (4) Sherry Henning (b) (4)	01 Feb 2021 22:54:31

US3062118

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '13:05'	Sherry Henning (b) (4)	01 Feb 2021 22:54:31
	(b) (4)	

US3062118

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:02:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '30 Jan 2021 13:05'	System	01 Feb 2021 22:54:31

US3062118

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

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Feb 2021 22:54:37
	(b) (4)	

US3062118

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

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '1'	System	01 Feb 2021 22:54:37

US3062118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	10 Feb 2021 00:48:03
	(b) (4)	

US3062118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
User entered '9 Feb 2021'	Colton King (b) (4)	10 Feb 2021 00:48:03

US3062118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colton King (b) (4)	10 Feb 2021 00:48:03

US3062118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
User entered empty.	(b) (4) Colton King (b) (4)	10 Feb 2021 00:48:03

US3062118

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	10 Feb 2021 00:48:09

US3062118

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '1'	System	10 Feb 2021 00:48:09

US3062118

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '1'	System	10 Feb 2021 00:48:09
DataPoint set to visible.	System	10 Feb 2021 00:48:09

US3062118

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Mar 2021 14:39:32
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '3 Mar 2021'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:39:32

US3062118

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[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 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Clinic (Clinic)'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:39:32

US3062118

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'OLD29'	System	05 Mar 2021 14:39:32

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '3 Mar 2021'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '10:13'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '3 Mar 2021 10:13'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '98.3' F	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Oral (Oral)'	Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered empty.	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '66'	Colton King (b) (4)	05 Mar 2021 14:41:02
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'bpm'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '14'	Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'breaths/min'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '113'	Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mmHg'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '63'	Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:02:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mmHg'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '3 Mar 2021'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '11:53'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '3 Mar 2021 11:53'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '98.8' F	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Oral (Oral)'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered empty.	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '62'	Colton King (b) (4)	05 Mar 2021 14:41:02
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'bpm'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '16'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'breaths/min'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '118'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mmHg'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '64'	Colton King (b) (4)	05 Mar 2021 14:41:02
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mmHg'	System	05 Mar 2021 14:41:02

US3062118

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Mar 2021 14:41:10
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered '3 Mar 2021'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:10

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4)	05 Mar 2021 14:41:37

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	05 Mar 2021 14:41:37
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

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 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	05 Mar 2021 14:41:37
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'mRNA-1273'	System	05 Mar 2021 14:41:37
DataPoint set to visible.	System	10 Feb 2021 00:48:09

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '3 Mar 2021'	Colton King (b) (4)	05 Mar 2021 14:41:37
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '11:21'	Colton King (b) (4)	05 Mar 2021 14:41:37
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '3 Mar 2021 11:21'	System	05 Mar 2021 14:41:37

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Colton King (b) (4)	05 Mar 2021 14:41:37
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'ONCE'	System	05 Mar 2021 14:41:37

US3062118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:02:24

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 14:41:37

US3062118

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Mar 2021 14:41:41
	(b) (4)	

US3062118

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered '1'	System	05 Mar 2021 14:41:41

US3062118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	11 Mar 2021 18:50:44
	(b) (4)	

US3062118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
	(b) (4)	
User entered '10 Mar 2021'	Janna Martinez (b) (4)	11 Mar 2021 18:50:44
	(b) (4)	

US3062118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	11 Mar 2021 18:50:44
	(b) (4)	

US3062118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:02:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	11 Mar 2021 18:50:44
	(b) (4)	

US3062118

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:11:40
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	11 Mar 2021 18:50:48
	(b) (4)	

US3062118

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:02:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:51:27
User entered 'I'	System	11 Mar 2021 18:50:48

US3062118

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Apr 2021 16:56:11
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '31 Mar 2021'	Colton King (b) (4)	01 Apr 2021 16:56:11
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Clinic (Clinic)'	Colton King (b) (4)	01 Apr 2021 16:56:11
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:02:24

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 16:56:11

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Apr 2021 18:37:43
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '31 Mar 2021'	Colton King (b) (4)	01 Apr 2021 18:37:43
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '10:07'	Colton King (b) (4)	01 Apr 2021 18:37:43
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 10:07'	System	01 Apr 2021 18:37:43

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '36.7' C	Colton King (b) (4)	01 Apr 2021 18:37:43
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:32:51
User entered 'Oral (Oral)'	Colton King (b) (4) (b) (4)	01 Apr 2021 18:37:43

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	01 Apr 2021 18:37:43
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '64'	Colton King (b) (4)	01 Apr 2021 18:37:43
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 18:37:43

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:32:51
User entered '16'	Colton King (b) (4) (b) (4)	01 Apr 2021 18:37:43

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 18:37:43

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '110'	Colton King (b) (4)	01 Apr 2021 18:37:43
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:37:43

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '67'	Colton King (b) (4)	01 Apr 2021 18:37:43
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:02:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:37:43

US3062118

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:32:51
User entered 'No (N)'	Colton King (b) (4) (b) (4)	01 Apr 2021 18:37:51

US3062118

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:02:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	01 Apr 2021 18:37:51
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Apr 2021 18:38:00
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '31 Mar 2021'	Colton King (b) (4)	01 Apr 2021 18:38:00
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '10:18'	Colton King (b) (4)	01 Apr 2021 18:38:00
	(b) (4)	

US3062118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:02:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 10:18'	System	01 Apr 2021 18:38:00

US3062118

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:02:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:39
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	29 Apr 2021 16:29:22
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Riley King (b) (4)	29 Apr 2021 16:29:22
	(b) (4)	
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:57:43
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Sep 2020 20:26:52
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:41
User entered 'USA-US090-2021-mRNA-1273-P301000013'	System	29 Apr 2021 21:12:33
User entered 'New'	(b) (4), (b) (6)	29 Apr 2021 21:12:33

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 08:26:26
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 08:26:26
User signature succeeded.	Richard Glover (b) (4) (b) (4)	29 Apr 2021 17:03:47
Data point term sent to Coder	System	29 Apr 2021 16:33:46
User entered 'Worsening arthritis right knee'	Riley King (b) (4) (b) (4)	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4) (b) (4)	29 Apr 2021 17:03:47
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '20 Apr 2021'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered empty.	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '20 Apr 2021'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered empty.	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4) (b) (4)	29 Apr 2021 17:03:47
User entered '0'	Riley King (b) (4) (b) (4)	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '1'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '20 Apr 2021'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '21 Apr 2021'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4) (b) (4)	29 Apr 2021 17:03:47
User entered empty.	Riley King (b) (4) (b) (4)	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4) [REDACTED]	29 Apr 2021 17:03:47
User entered '0'	(b) (4) Riley King (b) (4) [REDACTED]	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4) (b) (4)	29 Apr 2021 17:03:47
User entered '0'	Riley King (b) (4) (b) (4)	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4) (b) (4)	29 Apr 2021 17:03:47
User entered '0'	Riley King (b) (4) (b) (4)	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '1'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered empty.	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'During subject day 269 safety call subject reported having a right knee replacement. Subject received knee replacement for worsening arthritis of right knee, procedure performed at NMC health. Subject unsure of medications she received in the hospital at this time. Source and EDC updated. Release of records has been sent to subject for signature.'	Riley King (b) (4)	29 Apr 2021 16:33:07
	(b) (4)	

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 16:33:07

US3062118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:02:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 16:33:07

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:02:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	07 Aug 2020 14:37:23
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
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)	07 Aug 2020 14:48:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Aug 2020 14:48:19
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 14:47:18
User entered 'Multivitamin'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:59:32
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	15 Sep 2020 01:05:03
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Sep 2020 01:04:59
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 11:44:25
User entered 'No (N)'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Nutritional Supplement'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '1'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'tablet (TABLET)'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'once daily (QD)'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Oral (ORAL)'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 08:16:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Colton King (b) (4)	07 Aug 2020 14:47:41
answered with 'Correct per protocol ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 14:47:10
User entered '01 Jan 2018'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered '0'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

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

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered empty.	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	07 Aug 2020 14:47:10
	(b) (4)	

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:47:10

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:47:10

US3062118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:02:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 14:47:10

US3062118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:02:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:39
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	29 Apr 2021 16:33:17
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Riley King (b) (4)	29 Apr 2021 16:33:17
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:32:51
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Sep 2020 20:26:56
	(b) (4)	

US3062118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:02:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered '20 Apr 2021'	Riley King (b) (4)	29 Apr 2021 16:33:34
	(b) (4)	

US3062118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:02:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Right knee replacement'	Riley King (b) (4)	29 Apr 2021 16:33:34
	(b) (4)	

US3062118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:02:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered 'Adverse Event (AE)'	Riley King (b) (4)	29 Apr 2021 16:33:34
	(b) (4)	

US3062118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:02:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	29 Apr 2021 17:03:47
	(b) (4)	
User entered empty.	Riley King (b) (4)	29 Apr 2021 16:33:34
	(b) (4)	

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:55
User entered 'USA-US090-2021-MRNA-1273-P301000013'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Yes (Y)'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Yes (Y)'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Richard'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Glover'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered '700 Medical Center Dr.'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Newton'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'KS'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered '67114'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	29 Apr 2021 21:13:07

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:13:07

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:55
User entered 'USA-US090-2021-MRNA-1273-P301000013'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Yes (Y)'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

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[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Yes (Y)'	System	29 Apr 2021 21:12:33

US3062118

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

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[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'No (N)'	System	29 Apr 2021 21:12:33

US3062118

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Richard'	System	29 Apr 2021 21:12:33

US3062118

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Glover'	System	29 Apr 2021 21:12:33

US3062118

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[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered '700 Medical Center Dr.'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

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[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'Newton'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

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Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered 'KS'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:12:59
User entered '67114'	System	29 Apr 2021 21:12:33

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	29 Apr 2021 21:13:07

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:02:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:13:07

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:02:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '29/Apr/2021 17:13'	System	29 Apr 2021 21:13:07

US3062118

Folder: SAE USA-US090-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:02:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	29 Apr 2021 21:13:07