

US3262055 (Prod: AB Clinical Trials - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:15:52

All time stamps listed in this document are displayed in GMT

US3262055

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Participant ID

US3262055

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

US3262055

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:28:59

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Date of Informed Consent (<i>dd MMM yyyy</i>)	30 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:28:59

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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) 12 Feb 2021 21:28:59

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 21:28:59

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Condition	MITRAL VALVE PROLAPSE
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:28:59

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 JUL 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 14:40
Height (xxx.x)	74 in
Weight (xxx.x)	193.4 lb
BMI (xxx.x)	24.88301 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:28:59

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 JUL 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: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:28:59

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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

SALES MANAGER AT STORE

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) 12 Feb 2021 21:28:59

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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) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:28:59

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What was the date of randomization? (dd MMM yyyy) 30 JUL 2020

What was the participant's randomization number? 142400

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) 12 Feb 2021 21:28:59

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 JUL 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 14:40
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

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 (dd MMM yyyy)	30 JUL 2020
Time of assessment (00:00-23:59)	15:28 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 15:28
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:28:59

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:28:59

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Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 30 JUL 2020

What was the treatment time? (00:00-23:59) 14:58 (24 HR)

Treatment Date and Time (derived) 30 JUL 2020 14:58

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 JUL 2020
Collection time (00:00-23:59)	14:50 (24 HR)
Collection date and time (derived)	30 JUL 2020 14:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Collection date (<i>dd MMM yyyy</i>)			30 JUL 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:45	30 JUL 2020 14:45
Nasopharyngeal Swab 2	No		

US3262055

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

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 16:15:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 15:32

PC Open Date & Time

30 JUL 2020 15:18

PC Close Date & Time

30 JUL 2020 17:48

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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 97.6 °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	30 JUL 2020 23:30
PC Open Date & Time	30 JUL 2020 18:43
PC Close Date & Time	31 JUL 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

31 JUL 2020 16:41

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

01 AUG 2020 13:03

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 12:08

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 AUG 2020 15:06

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 14:43

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

05 AUG 2020 16:23

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 15:32

PC Open Date & Time

30 JUL 2020 15:18

PC Close Date & Time

30 JUL 2020 17:48

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

30 JUL 2020 23:31

PC Open Date & Time

30 JUL 2020 18:43

PC Close Date & Time

31 JUL 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 16:45

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 13:04

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 12:09

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 15:05

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 14:43

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 16:24

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 15:33
PC Open Date & Time	30 JUL 2020 15:18
PC Close Date & Time	30 JUL 2020 17:48

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 23:31
PC Open Date & Time	30 JUL 2020 18:43
PC Close Date & Time	31 JUL 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 16:47
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 13:05
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

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 ☒

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 12:09
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

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 ☒

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 15:06
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 14:44
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

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 ☒

PRODUCTION RELEASE (v12.003

52 of 1711

EAB) (1725)

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 16:24
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3262055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

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)	28 AUG 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

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)	28 AUG 2020
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:07
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3262055

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 AUG 2020

What was the treatment time? (00:00-23:59) 14:37 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 14:37

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

What was the frequency of the study treatment dosing? ONCE

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

US3262055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

14:20 (24 HR)

Collection date and time (derived)

28 AUG 2020 14:20

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:17	28 AUG 2020 14:17
Nasopharyngeal Swab 2	No		

US3262055

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 15:19

PC Open Date & Time

28 AUG 2020 14:57

PC Close Date & Time

28 AUG 2020 17:27

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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 98.8 °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	28 AUG 2020 23:59
PC Open Date & Time	28 AUG 2020 18:22
PC Close Date & Time	29 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

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	100.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 AUG 2020 22:53
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 23:40

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

31 AUG 2020 15:34

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

01 SEP 2020 17:24

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:16

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

03 SEP 2020 19:15

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 15:19

PC Open Date & Time

28 AUG 2020 14:57

PC Close Date & Time

28 AUG 2020 17:27

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

29 AUG 2020 00:00

PC Open Date & Time

28 AUG 2020 18:22

PC Close Date & Time

29 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 22:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 23:41

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 15:35

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 17:25

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 20:17

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:15

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 15:20
PC Open Date & Time	28 AUG 2020 14:57
PC Close Date & Time	28 AUG 2020 17:27

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 00:00
PC Open Date & Time	28 AUG 2020 18:22
PC Close Date & Time	29 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

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 ☒

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 22:55
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 23:41
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

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 ☒

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 15:36
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

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 ☒

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EAB) (1725)

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 17:25
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:17
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

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 ☒

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:15
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3262055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:58

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	VISIT3

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	25 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:45 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 12:45
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>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262055

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

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.

US3262055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 SEP 2020
Collection time (00:00-23:59)	13:02 (24 HR)
Collection date and time (derived)	25 SEP 2020 13:02

US3262055

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:28:59

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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	30 SEP 2020 15:48:50
Patient Cloud Open Date & Time	29 SEP 2020 00:01
Patient Cloud Close Date & Time	03 OCT 2020 23:59

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

07 OCT 2020 07:12:39

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 OCT 2020 12:01:36
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

04 NOV 2020 09:25:53

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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	10 NOV 2020 15:19:03
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 09:09:56

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 19:08:40

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 14:00:45

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 138

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Patient Cloud Open Date & Time	26 DEC 2020 00:01
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Patient Cloud Close Date & Time	30 DEC 2020 23:59
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US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 187

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 17:12:08
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 257

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 APR 2021 13:51:42
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 NOV 2021 00:01
Patient Cloud Close Date & Time	10 NOV 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 726

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

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

US3262055

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:15:52

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		12 MAR 2021 17:05:42

US3262055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:32:35

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:32:35

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	25 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 12:55
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	51 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262055

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

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.

US3262055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00-23:59)

13:04 (24 HR)

Collection date and time (derived)

25 FEB 2021 13:04

US3262055

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:54:42

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:54:42

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:54:42

Generated On: 09 Jun 2021 16:15:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3262055

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:54:42

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262055

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3262055

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:52

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"/>

US3262055

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:15:52

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3262055

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	10 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3262055

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Date of updated informed consent (dd MMM yyyy) 10 MAR 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 10 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3262055

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 MAR 2021
Collection time (00:00-23:59)	10:19 (24 HR)
Collection date and time (derived)	10 MAR 2021 10:19

US3262055

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 MAR 2021
Collection time (00:00 - 23:59)	10:22
Collection Date and Time (derived)	10 MAR 2021 10:22

US3262055

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:55:08

Generated On: 09 Jun 2021 16:15:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

AEID	USA-US069-2021-MRNA-1273-P30 1000001
Adverse event	SEQUELAE FROM METASTATIC MALIGNANCY OF UNKNOWN ORIGIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	05 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	11 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT PRESENTED TO HOSPITAL DUE TO SEQUELAE FROM METASTATIC MALIGNANCY OF UNKNOWN ORIGIN. THEY ARE ACTIVELY LOOKING FOR A MALIGNANCY SOURCE, BUT ALL TESTS HAVE COME BACK NEGATIVE.

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

AEID	
Adverse event	DECREASED APPETITE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 19:55:08

Generated On: 09 Jun 2021 16:15:52

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

Yes ☒

No ☐

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

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 19:55:08

Generated On: 09 Jun 2021 16:15:52

Name of Medication MEGASTROL

Prophylaxis Yes ☐
No ☒

Indication DECREASED APPETITE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 19:55:08

Generated On: 09 Jun 2021 16:15:52

	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)	10 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3262055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 19:55:08

Generated On: 09 Jun 2021 16:15:52

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3262055

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:15:52

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

US3262055

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:52

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 ☐

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US069-2021-MRNA-1273-P301000001
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US069-2021-MRNA-1273-P301000001
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/FEB/2021 10:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US069-2021-MRNA-1273-P301000001
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/MAR/2021 10:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US069-2021-MRNA-1273-P301000001
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/MAR/2021 10:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 16:07:36

Generated On: 09 Jun 2021 16:15:52

SAEID	USA-US069-2021-MRNA-1273-P301000001
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/MAR/2021 10:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3262055 (Prod: AB Clinical Trials - Hunt - PPDS)

US3262055

Form: Participant Creation

Generated On: 09 Jun 2021 16:15:52

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Dec 2020 17:36:06
User entered 'US3262055'	RWS_ENDPOINT	30 Jul 2020 21:49:22
	ENDPOINT (b) (4)	

US3262055

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:24:52
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:01

US3262055

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:24:52
User entered '30 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:49:23

US3262055

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:24:52
User entered 'Clinic (Clinic)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:01

US3262055

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'SCRN'	System	30 Jul 2020 22:10:01

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:19
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:49:24

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:24
User entered '64'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'YEARS'	System	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered '64'	System	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:26
User entered 'Male (M)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:29
User entered 'l'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:39:52
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:39:52
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:39:52
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:39:52
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:39:52
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:39:52
User entered empty.	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:39:52
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:39:52
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:34

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:48
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'Jul 2020'	System	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered '2020'	System	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:50
User entered 'Amendment 1 (1)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:51
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:08
User entered empty.	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:08
User entered empty.	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:27:54
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:21

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:08
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:49:23

US3262055

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'I'	System	30 Jul 2020 22:10:25

US3262055

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:08
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:25

US3262055

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:15:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:15
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:25:54

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:39
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve prolapse, LLT: Mitral valve prolapse - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 14:27:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 14:27:11
Data point term sent to Coder	System	06 Aug 2020 14:26:35
User entered 'MITRAL VALVE PROLAPSE'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:39
User entered 'UN UNK 1974'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:33:39
User entered '0'	Daisy Langarica (b) (4)	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:39
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:39
User entered empty.	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:39
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'Jan 1974'	System	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered '1974'	System	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered empty.	System	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered empty.	System	06 Aug 2020 14:26:14

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:27:07

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:27:07

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '14:40'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:27:07

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered '30 Jul 2020 14:40'	System	06 Aug 2020 14:27:07

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '74' in	Daisy Langarica (b) (4)	06 Aug 2020 14:27:07
DataPoint set to visible.	(b) (4) System	30 Jul 2020 22:10:25

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '193.4' lb	Daisy Langarica (b) (4)	06 Aug 2020 14:27:07
DataPoint set to visible.	(b) (4) System	30 Jul 2020 22:10:25

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
Amendment Manager: User entered '24.88301'	System	16 Sep 2020 23:39:20
User entered '24.9'	System	06 Aug 2020 14:27:07
DataPoint set to visible.	System	30 Jul 2020 22:10:25

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'kg/m2'	System	06 Aug 2020 14:27:07
DataPoint set to visible.	System	30 Jul 2020 22:10:25

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:36
User closed query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 08:56:05
Query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	17 Nov 2020 00:46:00
DataPoint Un-verified.	Daisy Langarica (b) (4) (b) (4)	17 Nov 2020 00:45:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	17 Nov 2020 00:45:50
User opened query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:37:54
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).		10 Nov 2020 20:37:54
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	24 Sep 2020 23:27:09
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:57:11

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '98.2' F	Daisy Langarica (b) (4)	06 Aug 2020 14:27:07
	(b) (4)	

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:36
DataPoint Un-verified.	Daisy Langarica (b) (4)	17 Nov 2020 00:45:50
User entered empty; reason for change Data Entry Error	(b) (4) Daisy Langarica (b) (4)	17 Nov 2020 00:45:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered 'Oral (Oral)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:27:07

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered empty.	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:27:07

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:36
DataPoint Un-verified.	Daisy Langarica (b) (4)	17 Nov 2020 00:45:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Nov 2020 00:45:50
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '75'	Daisy Langarica (b) (4)	06 Aug 2020 14:27:07
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'bpm'	System	06 Aug 2020 14:27:07

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:36
DataPoint Un-verified.	Daisy Langarica (b) (4)	17 Nov 2020 00:45:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Nov 2020 00:45:50
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '15'	Daisy Langarica (b) (4)	06 Aug 2020 14:27:07
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'breaths/min'	System	06 Aug 2020 14:27:07

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:36
DataPoint Un-verified.	Daisy Langarica (b) (4)	17 Nov 2020 00:45:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Daisy Langarica (b) (4)	17 Nov 2020 00:45:50
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '124'	Daisy Langarica (b) (4)	06 Aug 2020 14:27:07

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'mmHg'	System	06 Aug 2020 14:27:07

US3262055

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:40:36
DataPoint Un-verified.	Daisy Langarica (b) (4)	17 Nov 2020 00:45:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Nov 2020 00:45:50
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:35:57
User entered '88'	Daisy Langarica (b) (4)	06 Aug 2020 14:27:07
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User entered 'mmHg'	System	06 Aug 2020 14:27:07

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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:36:27
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:27:16

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 11:46:11
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 22:46:15
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:36:27
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:27:16

US3262055

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langerica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

US3262055

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

US3262055

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered 'SALES MANAGER AT STORE'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered 'I'	(b) (4) Daisy Langerica (b) (4) (b) (4)	06 Aug 2020 14:33:43

US3262055

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered '0'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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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)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered '0'	(b) (4) Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:37:30
User entered empty.	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:33:43

US3262055

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:10
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:56

US3262055

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:10
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:56

US3262055

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:10
User entered 'Clinic (Clinic)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:56

US3262055

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'VISIT1'	System	06 Aug 2020 14:32:56

US3262055

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:21
User entered '30 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:54:07

US3262055

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:26:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:26:19
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:38:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Jul 2020 21:54:07
User entered '142400' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:54:07

US3262055

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:26
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 21:54:07

US3262055

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:26
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:31:36

US3262055

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:26
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:31:36

US3262055

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:26
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:31:36

US3262055

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:26
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:31:36

US3262055

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:26
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:31:36

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 05:33:59
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'ND. Recorded at screening.' (Site from DM). DataPoint Un-verified.	Alia Bober (b) (4) (b) (4)	24 Sep 2020 23:27:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4)	24 Sep 2020 23:27:34
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '74' in reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 14:12:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	06 Aug 2020 14:40:26
User entered empty.	Daisy Langarica (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:25:45
DataPoint Un-verified.	Alia Bober (b) (4)	24 Sep 2020 23:27:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Alia Bober (b) (4)	24 Sep 2020 23:27:34
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '193.4' lb reason for change: Data Entry Error	Daisy Langarica (b) (4)	06 Aug 2020 14:40:26
User entered empty.	Daisy Langarica (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 05:33:59
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'ND. Recorded at screening.' (Site from DM). DataPoint Un-verified.	Alia Bober (b) (4) (b) (4)	24 Sep 2020 23:27:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4)	24 Sep 2020 23:27:34
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '74' in reason for change: Data Entry Error	(b) (4)	14 Aug 2020 14:12:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	06 Aug 2020 14:40:26
User entered empty.	Daisy Langarica (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:25:45
DataPoint Un-verified.	Alia Bober (b) (4)	24 Sep 2020 23:27:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Alia Bober (b) (4)	24 Sep 2020 23:27:34
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '193.4' lb reason for change: Data Entry Error	Daisy Langarica (b) (4)	06 Aug 2020 14:40:26
User entered empty.	Daisy Langarica (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '14:40'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered '30 Jul 2020 14:40'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '98.2' F	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered 'Oral (Oral)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered empty.	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '75'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'bpm'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '15'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'breaths/min'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '124'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'mmHg'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '88'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'mmHg'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 05:33:59
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:25:45
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'ND. Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	24 Sep 2020 23:27:42
DataPoint Un-verified.	Alia Bober (b) (4) (b) (4)	24 Sep 2020 23:27:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	24 Sep 2020 23:27:34
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 14:43:33
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '74' in reason for change: Data Entry Error		14 Aug 2020 14:12:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:26
User entered empty.	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:25:45
DataPoint Un-verified.	Alia Bober (b) (4)	24 Sep 2020 23:27:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Alia Bober (b) (4)	24 Sep 2020 23:27:34
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '193.4' lb reason for change: Data Entry Error	Daisy Langarica (b) (4)	06 Aug 2020 14:40:26
User entered empty.	Daisy Langarica (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
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) (4), (b) (6)	18 Aug 2020 17:44:04
DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 17:40:29
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'value correct' (Site from System).		14 Aug 2020 14:12:25
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		06 Aug 2020 14:40:07
User entered '15:28'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered '30 Jul 2020 15:28'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '98.1' F	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered 'Oral (Oral)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered empty.	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '71'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'bpm'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '16'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'breaths/min'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '115'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'mmHg'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:29
User entered '78'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'mmHg'	System	06 Aug 2020 14:40:07

US3262055

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:36
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:31:49

US3262055

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:36
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:31:49

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:43:09
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:43:09
User entered empty.	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:43:09
User entered empty.	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'MRNA-1273 OR PLACEBO'	System	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:43:09
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:43:09
User entered '14:58'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered '30 Jul 2020 14:58'	System	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:43:09
User entered 'Left Arm (LEFT ARM)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
DataPoint Verified.		17 Aug 2020 17:43:09
User entered 'ONCE'	System	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'INTRAMUSCULAR'	System	30 Jul 2020 22:10:54

US3262055

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:09
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:24

US3262055

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:09
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:24

US3262055

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:09
User entered '14:50'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:24

US3262055

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered '30 Jul 2020 14:50'	System	06 Aug 2020 14:32:24

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:19
User entered '30 Jul 2020'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:19
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:19
User entered '14:45'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered '30 Jul 2020 14:45'	System	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Daisy Langarica (b) (4)	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:19
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:19
User entered empty.	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered empty.	System	06 Aug 2020 14:32:44

US3262055

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:14:28
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	30 Jul 2020 22:11:04

US3262055

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered '1'	System	30 Jul 2020 22:11:04

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:31:49', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '06177aaa-cacd-4791-bd82-a4c71cc36c58'	System	30 Jul 2020 22:32:12
User entered 'Yes (Y)'	System	30 Jul 2020 22:32:12

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:31:57', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '06177aaa-cacd-4791-bd82-a4c71cc36c58'	System	30 Jul 2020 22:32:12
User entered '98.1'	System	30 Jul 2020 22:32:12

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:02', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '06177aaa-cacd-4791-bd82-a4c71cc36c58'	System	30 Jul 2020 22:32:12
User entered 'No (N)'	System	30 Jul 2020 22:32:12

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:08', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '06177aaa-cacd-4791-bd82-a4c71cc36c58'	System	30 Jul 2020 22:32:12
User entered '30 Jul 2020 15:32'	System	30 Jul 2020 22:32:12

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 15:18'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 17:48'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:30:14', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '67a5f65c-0b2d-49ef-936a-554aac70b31b'	System	31 Jul 2020 06:30:39
User entered 'Yes (Y)'	System	31 Jul 2020 06:30:39

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:30:24', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '67a5f65c-0b2d-49ef-936a-554aac70b31b'	System	31 Jul 2020 06:30:39
User entered '97.6'	System	31 Jul 2020 06:30:39

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:30:27', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '67a5f65c-0b2d-49ef-936a-554aac70b31b'	System	31 Jul 2020 06:30:39
User entered 'No (N)'	System	31 Jul 2020 06:30:39

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:30:37', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '67a5f65c-0b2d-49ef-936a-554aac70b31b'	System	31 Jul 2020 06:30:39
User entered '30 Jul 2020 23:30'	System	31 Jul 2020 06:30:39

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 18:43'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 2'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:41:30', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f1588423-a301-418d-8781-23087a3f957e'	System	31 Jul 2020 23:41:53
User entered 'Yes (Y)'	System	31 Jul 2020 23:41:53

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:41:41', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f1588423-a301-418d-8781-23087a3f957e'	System	31 Jul 2020 23:41:53
User entered '98.9'	System	31 Jul 2020 23:41:53

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:41:44', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f1588423-a301-418d-8781-23087a3f957e'	System	31 Jul 2020 23:41:53
User entered 'No (N)'	System	31 Jul 2020 23:41:53

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:41:51', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f1588423-a301-418d-8781-23087a3f957e' User entered '31 Jul 2020 16:41'	System	31 Jul 2020 23:41:53
	System	31 Jul 2020 23:41:53

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 3'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:03:38', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6873342f-4e3a-4b79-b92e-a7883c9179de'	System	01 Aug 2020 20:04:01
User entered 'Yes (Y)'	System	01 Aug 2020 20:04:01

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:03:47', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6873342f-4e3a-4b79-b92e-a7883c9179de' User entered '97.9'	System	01 Aug 2020 20:04:01
	System	01 Aug 2020 20:04:01

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:03:50', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6873342f-4e3a-4b79-b92e-a7883c9179de'	System	01 Aug 2020 20:04:01
User entered 'No (N)'	System	01 Aug 2020 20:04:01

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:03:58', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6873342f-4e3a-4b79-b92e-a7883c9179de'	System	01 Aug 2020 20:04:01
User entered '01 Aug 2020 13:03'	System	01 Aug 2020 20:04:01

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 4'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:08:30', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fa32f4be-5231-4106-9183-ca91c933e7c9'	System	02 Aug 2020 19:08:46
User entered 'Yes (Y)'	System	02 Aug 2020 19:08:46

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:08:38', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fa32f4be-5231-4106-9183-ca91c933e7c9'	System	02 Aug 2020 19:08:46
User entered '97.5'	System	02 Aug 2020 19:08:46

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:08:41', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fa32f4be-5231-4106-9183-ca91c933e7c9'	System	02 Aug 2020 19:08:46
User entered 'No (N)'	System	02 Aug 2020 19:08:46

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:08:45', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fa32f4be-5231-4106-9183-ca91c933e7c9'	System	02 Aug 2020 19:08:46
User entered '02 Aug 2020 12:08'	System	02 Aug 2020 19:08:46

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 5'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:39', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73f90437-df39-4826-bf04-1661dd5a3fb7'	System	03 Aug 2020 22:06:58
User entered 'Yes (Y)'	System	03 Aug 2020 22:06:58

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:47', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73f90437-df39-4826-bf04-1661dd5a3fb7'	System	03 Aug 2020 22:06:58
User entered '97.6'	System	03 Aug 2020 22:06:58

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:51', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73f90437-df39-4826-bf04-1661dd5a3fb7'	System	03 Aug 2020 22:06:58
User entered 'No (N)'	System	03 Aug 2020 22:06:58

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:55', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73f90437-df39-4826-bf04-1661dd5a3fb7'	System	03 Aug 2020 22:06:58
User entered '03 Aug 2020 15:06'	System	03 Aug 2020 22:06:58

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 6'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:03', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'da2bbef5-0623-466c-af0a-2c1d89b32123'	System	04 Aug 2020 21:43:20
User entered 'Yes (Y)'	System	04 Aug 2020 21:43:20

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:11', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'da2bbef5-0623-466c-af0a-2c1d89b32123'	System	04 Aug 2020 21:43:20
User entered '97.5'	System	04 Aug 2020 21:43:20

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:14', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'da2bbef5-0623-466c-af0a-2c1d89b32123'	System	04 Aug 2020 21:43:20
User entered 'No (N)'	System	04 Aug 2020 21:43:20

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:18', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'da2bbef5-0623-466c-af0a-2c1d89b32123'	System	04 Aug 2020 21:43:20
User entered '04 Aug 2020 14:43'	System	04 Aug 2020 21:43:20

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 7'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:23:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '37e0c436-f544-4629-80e8-2e8d55d7c60d'	System	05 Aug 2020 23:23:46
User entered 'Yes (Y)'	System	05 Aug 2020 23:23:46

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:23:33', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '37e0c436-f544-4629-80e8-2e8d55d7c60d' User entered '98.9'	System	05 Aug 2020 23:23:46
	System	05 Aug 2020 23:23:46

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:23:36', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '37e0c436-f544-4629-80e8-2e8d55d7c60d'	System	05 Aug 2020 23:23:46
User entered 'No (N)'	System	05 Aug 2020 23:23:46

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:23:43', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '37e0c436-f544-4629-80e8-2e8d55d7c60d'	System	05 Aug 2020 23:23:46
User entered '05 Aug 2020 16:23'	System	05 Aug 2020 23:23:46

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:22', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'cca4a1e6-05c4-4992-914d-45110251ef90'	System	30 Jul 2020 22:32:44
User entered 'None (1)'	System	30 Jul 2020 22:32:44

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:26', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'cca4a1e6-05c4-4992-914d-45110251ef90'	System	30 Jul 2020 22:32:44
User entered 'No (N)'	System	30 Jul 2020 22:32:44

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:30', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'cca4a1e6-05c4-4992-914d-45110251ef90'	System	30 Jul 2020 22:32:44
User entered 'No (N)'	System	30 Jul 2020 22:32:44

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:36', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'cca4a1e6-05c4-4992-914d-45110251ef90'	System	30 Jul 2020 22:32:44
User entered 'None (1)'	System	30 Jul 2020 22:32:44

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:41', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'cca4a1e6-05c4-4992-914d-45110251ef90'	System	30 Jul 2020 22:32:44
User entered '30 Jul 2020 15:32'	System	30 Jul 2020 22:32:44

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 15:18'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 17:48'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:30:46', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5aefebb1-8423-48c4-bbcc-d3eb62b679e9'	System	31 Jul 2020 06:31:07
User entered 'None (1)'	System	31 Jul 2020 06:31:07

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:30:50', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5aefebb1-8423-48c4-bbcc-d3eb62b679e9'	System	31 Jul 2020 06:31:07
User entered 'No (N)'	System	31 Jul 2020 06:31:07

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:30:55', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5aefebb1-8423-48c4-bbcc-d3eb62b679e9'	System	31 Jul 2020 06:31:07
User entered 'No (N)'	System	31 Jul 2020 06:31:07

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:30:59', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5aefebb1-8423-48c4-bbcc-d3eb62b679e9'	System	31 Jul 2020 06:31:07
User entered 'None (1)'	System	31 Jul 2020 06:31:07

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:05', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5aefebb1-8423-48c4-bbcc-d3eb62b679e9' User entered '30 Jul 2020 23:31'	System	31 Jul 2020 06:31:07
	System	31 Jul 2020 06:31:07

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 18:43'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 2'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:44:21', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05d80bea-dc91-4638-8b4e-805ddd83f10a'	System	31 Jul 2020 23:45:55
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 23:45:55

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:44:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05d80bea-dc91-4638-8b4e-805ddd83f10a'	System	31 Jul 2020 23:45:55
User entered 'Yes (Y)'	System	31 Jul 2020 23:45:55

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:45:24', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05d80bea-dc91-4638-8b4e-805ddd83f10a'	System	31 Jul 2020 23:45:55
User entered '10'	System	31 Jul 2020 23:45:55

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:45:30', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05d80bea-dc91-4638-8b4e-805ddd83f10a'	System	31 Jul 2020 23:45:55
User entered 'No (N)'	System	31 Jul 2020 23:45:55

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:45:40', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05d80bea-dc91-4638-8b4e-805ddd83f10a'	System	31 Jul 2020 23:45:55
User entered 'None (1)'	System	31 Jul 2020 23:45:55

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:45:54', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05d80bea-dc91-4638-8b4e-805ddd83f10a'	System	31 Jul 2020 23:45:55
User entered '31 Jul 2020 16:45'	System	31 Jul 2020 23:45:55

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 3'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:10', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '0ab786f1-1b56-4b08-98a6-769b413f35c5'	System	01 Aug 2020 20:04:38
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 20:04:38

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:14', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '0ab786f1-1b56-4b08-98a6-769b413f35c5'	System	01 Aug 2020 20:04:38
User entered 'No (N)'	System	01 Aug 2020 20:04:38

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:18', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '0ab786f1-1b56-4b08-98a6-769b413f35c5'	System	01 Aug 2020 20:04:38
User entered 'No (N)'	System	01 Aug 2020 20:04:38

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:26', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '0ab786f1-1b56-4b08-98a6-769b413f35c5'	System	01 Aug 2020 20:04:38
User entered 'None (1)'	System	01 Aug 2020 20:04:38

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:37', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '0ab786f1-1b56-4b08-98a6-769b413f35c5'	System	01 Aug 2020 20:04:38
User entered '01 Aug 2020 13:04'	System	01 Aug 2020 20:04:38

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 4'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:04', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6b0eb88e-ff9a-4ffb-9c08-1086e7ba89d7'	System	02 Aug 2020 19:09:20
User entered 'Does not interfere with activity (2)'	System	02 Aug 2020 19:09:20

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:07', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6b0eb88e-ff9a-4ffb-9c08-1086e7ba89d7'	System	02 Aug 2020 19:09:20
User entered 'No (N)'	System	02 Aug 2020 19:09:20

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:10', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6b0eb88e-ff9a-4ffb-9c08-1086e7ba89d7'	System	02 Aug 2020 19:09:20
User entered 'No (N)'	System	02 Aug 2020 19:09:20

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:15', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6b0eb88e-ff9a-4ffb-9c08-1086e7ba89d7'	System	02 Aug 2020 19:09:20
User entered 'None (1)'	System	02 Aug 2020 19:09:20

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:19', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6b0eb88e-ff9a-4ffb-9c08-1086e7ba89d7'	System	02 Aug 2020 19:09:20
User entered '02 Aug 2020 12:09'	System	02 Aug 2020 19:09:20

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 5'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:05:36', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8f3b4817-a4b5-4de4-9daa-9f3b9c6e5cc2'	System	03 Aug 2020 22:05:52
User entered 'None (1)'	System	03 Aug 2020 22:05:52

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:05:39', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8f3b4817-a4b5-4de4-9daa-9f3b9c6e5cc2'	System	03 Aug 2020 22:05:52
User entered 'No (N)'	System	03 Aug 2020 22:05:52

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:05:43', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8f3b4817-a4b5-4de4-9daa-9f3b9c6e5cc2'	System	03 Aug 2020 22:05:52
User entered 'No (N)'	System	03 Aug 2020 22:05:52

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:05:46', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8f3b4817-a4b5-4de4-9daa-9f3b9c6e5cc2'	System	03 Aug 2020 22:05:52
User entered 'None (1)'	System	03 Aug 2020 22:05:52

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:05:51', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8f3b4817-a4b5-4de4-9daa-9f3b9c6e5cc2'	System	03 Aug 2020 22:05:52
User entered '03 Aug 2020 15:05'	System	03 Aug 2020 22:05:52

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 6'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '913d4311-4faa-4c1b-8690-8c0bd18408f8'	System	04 Aug 2020 21:43:39
User entered 'None (1)'	System	04 Aug 2020 21:43:39

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:26', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '913d4311-4faa-4c1b-8690-8c0bd18408f8'	System	04 Aug 2020 21:43:39
User entered 'No (N)'	System	04 Aug 2020 21:43:39

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:29', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '913d4311-4faa-4c1b-8690-8c0bd18408f8'	System	04 Aug 2020 21:43:39
User entered 'No (N)'	System	04 Aug 2020 21:43:39

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:33', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '913d4311-4faa-4c1b-8690-8c0bd18408f8'	System	04 Aug 2020 21:43:39
User entered 'None (1)'	System	04 Aug 2020 21:43:39

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:37', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '913d4311-4faa-4c1b-8690-8c0bd18408f8'	System	04 Aug 2020 21:43:39
User entered '04 Aug 2020 14:43'	System	04 Aug 2020 21:43:39

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 7'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:23:49', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fab0ae22-082f-4538-8ee3-3246507eec7a'	System	05 Aug 2020 23:24:11
User entered 'None (1)'	System	05 Aug 2020 23:24:11

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:23:53', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fab0ae22-082f-4538-8ee3-3246507eec7a'	System	05 Aug 2020 23:24:11
User entered 'No (N)'	System	05 Aug 2020 23:24:11

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:23:56', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fab0ae22-082f-4538-8ee3-3246507eec7a'	System	05 Aug 2020 23:24:11
User entered 'No (N)'	System	05 Aug 2020 23:24:11

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:06', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fab0ae22-082f-4538-8ee3-3246507eec7a'	System	05 Aug 2020 23:24:11
User entered 'None (1)'	System	05 Aug 2020 23:24:11

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:10', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fab0ae22-082f-4538-8ee3-3246507eec7a'	System	05 Aug 2020 23:24:11
User entered '05 Aug 2020 16:24'	System	05 Aug 2020 23:24:11

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:52', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '21244454-2dc1-479d-a3c4-7a8b56a5f4b0'	System	30 Jul 2020 22:33:33
User entered 'None (0)'	System	30 Jul 2020 22:33:33

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:32:56', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '21244454-2dc1-479d-a3c4-7a8b56a5f4b0'	System	30 Jul 2020 22:33:33
User entered 'None (0)'	System	30 Jul 2020 22:33:33

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:33:02', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '21244454-2dc1-479d-a3c4-7a8b56a5f4b0'	System	30 Jul 2020 22:33:33
User entered 'None (0)'	System	30 Jul 2020 22:33:33

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:33:06', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '21244454-2dc1-479d-a3c4-7a8b56a5f4b0'	System	30 Jul 2020 22:33:33
User entered 'None (0)'	System	30 Jul 2020 22:33:33

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:33:11', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '21244454-2dc1-479d-a3c4-7a8b56a5f4b0'	System	30 Jul 2020 22:33:33
User entered 'None (0)'	System	30 Jul 2020 22:33:33

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:33:14', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '21244454-2dc1-479d-a3c4-7a8b56a5f4b0'	System	30 Jul 2020 22:33:33
User entered 'None (0)'	System	30 Jul 2020 22:33:33

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:33:20', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '21244454-2dc1-479d-a3c4-7a8b56a5f4b0'	System	30 Jul 2020 22:33:33
User entered 'No (N)'	System	30 Jul 2020 22:33:33

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T15:33:31', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '21244454-2dc1-479d-a3c4-7a8b56a5f4b0'	System	30 Jul 2020 22:33:33
User entered '30 Jul 2020 15:33'	System	30 Jul 2020 22:33:33

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 15:18'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 17:48'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:16', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '118d7b95-9a7c-4e83-9a4a-c9b1e1dfba78'	System	31 Jul 2020 06:31:58
User entered 'None (0)'	System	31 Jul 2020 06:31:58

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:30', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '118d7b95-9a7c-4e83-9a4a-c9b1e1dfba78'	System	31 Jul 2020 06:31:58
User entered 'None (0)'	System	31 Jul 2020 06:31:58

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:33', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '118d7b95-9a7c-4e83-9a4a-c9b1e1dfba78'	System	31 Jul 2020 06:31:58
User entered 'None (0)'	System	31 Jul 2020 06:31:58

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:36', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '118d7b95-9a7c-4e83-9a4a-c9b1e1dfba78'	System	31 Jul 2020 06:31:58
User entered 'None (0)'	System	31 Jul 2020 06:31:58

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:39', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '118d7b95-9a7c-4e83-9a4a-c9b1e1dfba78'	System	31 Jul 2020 06:31:58
User entered 'None (0)'	System	31 Jul 2020 06:31:58

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:42', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '118d7b95-9a7c-4e83-9a4a-c9b1e1dfba78'	System	31 Jul 2020 06:31:58
User entered 'None (0)'	System	31 Jul 2020 06:31:58

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:48', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '118d7b95-9a7c-4e83-9a4a-c9b1e1dfba78'	System	31 Jul 2020 06:31:58
User entered 'No (N)'	System	31 Jul 2020 06:31:58

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-30T23:31:56', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '118d7b95-9a7c-4e83-9a4a-c9b1e1dfba78'	System	31 Jul 2020 06:31:58
User entered '30 Jul 2020 23:31'	System	31 Jul 2020 06:31:58

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Jul 2020 18:43'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 2'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:46:01', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ced2f02e-c3e5-4bb7-9f25-89252e330725'	System	31 Jul 2020 23:47:36
User entered 'None (0)'	System	31 Jul 2020 23:47:36

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:47:11', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ced2f02e-c3e5-4bb7-9f25-89252e330725'	System	31 Jul 2020 23:47:36
User entered 'None (0)'	System	31 Jul 2020 23:47:36

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:46:19', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ced2f02e-c3e5-4bb7-9f25-89252e330725'	System	31 Jul 2020 23:47:36
User entered 'None (0)'	System	31 Jul 2020 23:47:36

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:46:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ced2f02e-c3e5-4bb7-9f25-89252e330725'	System	31 Jul 2020 23:47:36
User entered 'None (0)'	System	31 Jul 2020 23:47:36

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:46:28', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ced2f02e-c3e5-4bb7-9f25-89252e330725'	System	31 Jul 2020 23:47:36
User entered 'None (0)'	System	31 Jul 2020 23:47:36

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:46:40', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ced2f02e-c3e5-4bb7-9f25-89252e330725'	System	31 Jul 2020 23:47:36
User entered 'No interference with activity (1)'	System	31 Jul 2020 23:47:36

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:46:47', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ced2f02e-c3e5-4bb7-9f25-89252e330725'	System	31 Jul 2020 23:47:36
User entered 'No (N)'	System	31 Jul 2020 23:47:36

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-07-31T16:47:34', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ced2f02e-c3e5-4bb7-9f25-89252e330725'	System	31 Jul 2020 23:47:36
User entered '31 Jul 2020 16:47'	System	31 Jul 2020 23:47:36

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 3'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:44', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9513447-4e3f-42da-9d0a-c7c57748aaf9'	System	01 Aug 2020 20:05:31
User entered 'None (0)'	System	01 Aug 2020 20:05:31

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:49', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9513447-4e3f-42da-9d0a-c7c57748aaf9'	System	01 Aug 2020 20:05:31
User entered 'None (0)'	System	01 Aug 2020 20:05:31

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:52', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9513447-4e3f-42da-9d0a-c7c57748aaf9'	System	01 Aug 2020 20:05:31
User entered 'None (0)'	System	01 Aug 2020 20:05:31

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:04:58', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9513447-4e3f-42da-9d0a-c7c57748aaf9'	System	01 Aug 2020 20:05:31
User entered 'None (0)'	System	01 Aug 2020 20:05:31

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:05:05', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9513447-4e3f-42da-9d0a-c7c57748aaf9'	System	01 Aug 2020 20:05:31
User entered 'None (0)'	System	01 Aug 2020 20:05:31

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:05:12', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9513447-4e3f-42da-9d0a-c7c57748aaf9'	System	01 Aug 2020 20:05:31
User entered 'None (0)'	System	01 Aug 2020 20:05:31

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:05:16', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9513447-4e3f-42da-9d0a-c7c57748aaf9'	System	01 Aug 2020 20:05:31
User entered 'No (N)'	System	01 Aug 2020 20:05:31

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-01T13:05:28', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9513447-4e3f-42da-9d0a-c7c57748aaf9'	System	01 Aug 2020 20:05:31
User entered '01 Aug 2020 13:05'	System	01 Aug 2020 20:05:31

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 4'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:26', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fee601c7-b23f-48db-b487-240f2cc05890'	System	02 Aug 2020 19:09:57
User entered 'None (0)'	System	02 Aug 2020 19:09:57

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:30', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fee601c7-b23f-48db-b487-240f2cc05890'	System	02 Aug 2020 19:09:57
User entered 'None (0)'	System	02 Aug 2020 19:09:57

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:33', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fee601c7-b23f-48db-b487-240f2cc05890'	System	02 Aug 2020 19:09:57
User entered 'None (0)'	System	02 Aug 2020 19:09:57

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:36', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fee601c7-b23f-48db-b487-240f2cc05890'	System	02 Aug 2020 19:09:57
User entered 'None (0)'	System	02 Aug 2020 19:09:57

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:39', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fee601c7-b23f-48db-b487-240f2cc05890'	System	02 Aug 2020 19:09:57
User entered 'None (0)'	System	02 Aug 2020 19:09:57

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:43', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fee601c7-b23f-48db-b487-240f2cc05890'	System	02 Aug 2020 19:09:57
User entered 'None (0)'	System	02 Aug 2020 19:09:57

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:48', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fee601c7-b23f-48db-b487-240f2cc05890'	System	02 Aug 2020 19:09:57
User entered 'No (N)'	System	02 Aug 2020 19:09:57

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-02T12:09:55', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'fee601c7-b23f-48db-b487-240f2cc05890'	System	02 Aug 2020 19:09:57
User entered '02 Aug 2020 12:09'	System	02 Aug 2020 19:09:57

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 5'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:05:57', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5504b569-6d2d-483f-80ad-daa08e308f11'	System	03 Aug 2020 22:06:25
User entered 'None (0)'	System	03 Aug 2020 22:06:25

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:02', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5504b569-6d2d-483f-80ad-daa08e308f11'	System	03 Aug 2020 22:06:25
User entered 'None (0)'	System	03 Aug 2020 22:06:25

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:05', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5504b569-6d2d-483f-80ad-daa08e308f11'	System	03 Aug 2020 22:06:25
User entered 'None (0)'	System	03 Aug 2020 22:06:25

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:09', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5504b569-6d2d-483f-80ad-daa08e308f11'	System	03 Aug 2020 22:06:25
User entered 'None (0)'	System	03 Aug 2020 22:06:25

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:14', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5504b569-6d2d-483f-80ad-daa08e308f11'	System	03 Aug 2020 22:06:25
User entered 'None (0)'	System	03 Aug 2020 22:06:25

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:17', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5504b569-6d2d-483f-80ad-daa08e308f11'	System	03 Aug 2020 22:06:25
User entered 'None (0)'	System	03 Aug 2020 22:06:25

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:20', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5504b569-6d2d-483f-80ad-daa08e308f11'	System	03 Aug 2020 22:06:25
User entered 'No (N)'	System	03 Aug 2020 22:06:25

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-03T15:06:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5504b569-6d2d-483f-80ad-daa08e308f11'	System	03 Aug 2020 22:06:25
User entered '03 Aug 2020 15:06'	System	03 Aug 2020 22:06:25

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 6'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:42', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ef769cbb-8eeb-4a8a-98e4-815730820b02'	System	04 Aug 2020 21:44:07
User entered 'None (0)'	System	04 Aug 2020 21:44:07

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:48', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ef769cbb-8eeb-4a8a-98e4-815730820b02'	System	04 Aug 2020 21:44:07
User entered 'None (0)'	System	04 Aug 2020 21:44:07

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:51', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ef769cbb-8eeb-4a8a-98e4-815730820b02'	System	04 Aug 2020 21:44:07
User entered 'None (0)'	System	04 Aug 2020 21:44:07

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:53', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ef769cbb-8eeb-4a8a-98e4-815730820b02'	System	04 Aug 2020 21:44:07
User entered 'None (0)'	System	04 Aug 2020 21:44:07

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:56', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ef769cbb-8eeb-4a8a-98e4-815730820b02'	System	04 Aug 2020 21:44:07
User entered 'None (0)'	System	04 Aug 2020 21:44:07

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:43:59', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ef769cbb-8eeb-4a8a-98e4-815730820b02'	System	04 Aug 2020 21:44:07
User entered 'None (0)'	System	04 Aug 2020 21:44:07

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:44:02', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ef769cbb-8eeb-4a8a-98e4-815730820b02'	System	04 Aug 2020 21:44:07
User entered 'No (N)'	System	04 Aug 2020 21:44:07

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-04T14:44:06', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ef769cbb-8eeb-4a8a-98e4-815730820b02'	System	04 Aug 2020 21:44:07
User entered '04 Aug 2020 14:44'	System	04 Aug 2020 21:44:07

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 7'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:15', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ad3514e8-aa8c-4f54-ac8b-c9ca3fd3f934'	System	05 Aug 2020 23:24:43
User entered 'None (0)'	System	05 Aug 2020 23:24:43

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:18', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ad3514e8-aa8c-4f54-ac8b-c9ca3fd3f934'	System	05 Aug 2020 23:24:43
User entered 'None (0)'	System	05 Aug 2020 23:24:43

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:20', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ad3514e8-aa8c-4f54-ac8b-c9ca3fd3f934'	System	05 Aug 2020 23:24:43
User entered 'None (0)'	System	05 Aug 2020 23:24:43

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ad3514e8-aa8c-4f54-ac8b-c9ca3fd3f934'	System	05 Aug 2020 23:24:43
User entered 'None (0)'	System	05 Aug 2020 23:24:43

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ad3514e8-aa8c-4f54-ac8b-c9ca3fd3f934'	System	05 Aug 2020 23:24:43
User entered 'None (0)'	System	05 Aug 2020 23:24:43

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:29', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ad3514e8-aa8c-4f54-ac8b-c9ca3fd3f934'	System	05 Aug 2020 23:24:43
User entered 'None (0)'	System	05 Aug 2020 23:24:43

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:34', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ad3514e8-aa8c-4f54-ac8b-c9ca3fd3f934'	System	05 Aug 2020 23:24:43
User entered 'No (N)'	System	05 Aug 2020 23:24:43

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-05T16:24:39', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ad3514e8-aa8c-4f54-ac8b-c9ca3fd3f934'	System	05 Aug 2020 23:24:43
User entered '05 Aug 2020 16:24'	System	05 Aug 2020 23:24:43

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 22:10:54

US3262055

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:54:24
User entered 'Yes (Y)'		14 Aug 2020 16:19:46

US3262055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:54:24
User entered '06 Aug 2020'		14 Aug 2020 16:19:46

US3262055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:54:24
User entered 'Contact Made (CONTACT MADE)'		14 Aug 2020 16:19:46

US3262055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:54:24
User entered empty.		14 Aug 2020 16:19:46

US3262055

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:54:53
User entered 'Yes (Y)'		14 Aug 2020 16:19:53

US3262055

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:50
User entered 'I'	System	14 Aug 2020 16:19:53

US3262055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:40
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:55:59
User entered 'Yes (Y)'		14 Aug 2020 16:20:12

US3262055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:40
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:55:59
User entered '14 Aug 2020'		14 Aug 2020 16:20:12

US3262055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:40
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:55:59
User entered 'Contact Made (CONTACT MADE)'		14 Aug 2020 16:20:12

US3262055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:40
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:55:59
User entered empty.		14 Aug 2020 16:20:12

US3262055

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:40
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:56:06
User entered 'Yes (Y)'		14 Aug 2020 16:20:18

US3262055

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:26:40
User entered 'I'	System	14 Aug 2020 16:20:18

US3262055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:02:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:59:58
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:23:55

US3262055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:02:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:59:58
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered '20 Aug 2020'	(b) (4) Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:23:55

US3262055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:02:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:59:58
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:23:55

US3262055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:02:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:59:58
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered empty.	(b) (4) Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:23:55

US3262055

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:02:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:58:49
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 21:46:13

US3262055

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:02:55
User entered 'I'	System	28 Aug 2020 21:46:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:02
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:46:15

US3262055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:02
User entered '28 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:46:15

US3262055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:02
User entered 'Clinic (Clinic)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:46:15

US3262055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'VISIT2'	System	28 Aug 2020 22:46:15

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4)	28 Aug 2020 23:01:36
	(b) (4)	

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '28 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '14:15'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '28 Aug 2020 14:15'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '98.4' F	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered 'Oral (Oral)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered empty.	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '89'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'bpm'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '14'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'breaths/min'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '107'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'mmHg'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '72'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'mmHg'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '28 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '15:07'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '28 Aug 2020 15:07'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '98.2' F	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered 'Oral (Oral)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered empty.	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '86'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'bpm'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '12'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'breaths/min'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '111'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'mmHg'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:37
User entered '77'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'mmHg'	System	28 Aug 2020 23:01:36

US3262055

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:53
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:51

US3262055

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:53
User entered '28 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:01:51

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:15
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:15
User entered empty.	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:15
User entered empty.	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:15
User entered '28 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:15
User entered '14:37'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '28 Aug 2020 14:37'	System	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:15
User entered 'Left Arm (LEFT ARM)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:54:15
User entered 'ONCE'	System	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 22:14:13

US3262055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:43
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:23

US3262055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:43
User entered '28 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:23

US3262055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:43
User entered '14:20'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:23

US3262055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '28 Aug 2020 14:20'	System	28 Aug 2020 23:02:23

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:15:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:54
User entered '28 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Daisy Langarica (b) (4)	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:54
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:54
User entered '14:17'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '28 Aug 2020 14:17'	System	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Daisy Langarica (b) (4)	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:54
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:54:54
User entered empty.	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered empty.	System	28 Aug 2020 23:02:08

US3262055

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:55:04
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	28 Aug 2020 23:02:27

US3262055

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '1'	System	28 Aug 2020 23:02:27

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:18:48', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'eff2e92c-2931-4b1e-80b0-81962ba35649'	System	28 Aug 2020 22:19:05
User entered 'Yes (Y)'	System	28 Aug 2020 22:19:05

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:18:55', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'eff2e92c-2931-4b1e-80b0-81962ba35649'	System	28 Aug 2020 22:19:05
User entered '98.2'	System	28 Aug 2020 22:19:05

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:18:59', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'eff2e92c-2931-4b1e-80b0-81962ba35649'	System	28 Aug 2020 22:19:05
User entered 'No (N)'	System	28 Aug 2020 22:19:05

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:03', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'eff2e92c-2931-4b1e-80b0-81962ba35649'	System	28 Aug 2020 22:19:05
User entered '28 Aug 2020 15:19'	System	28 Aug 2020 22:19:05

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 14:57'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 17:27'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T23:59:19', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '9fa1afda-af78-45b3-bf7e-3b327afcb24e'	System	29 Aug 2020 06:59:41
User entered 'Yes (Y)'	System	29 Aug 2020 06:59:41

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T23:59:30', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '9fa1afda-af78-45b3-bf7e-3b327afcb24e'	System	29 Aug 2020 06:59:41
User entered '98.8'	System	29 Aug 2020 06:59:41

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T23:59:34', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '9fa1afda-af78-45b3-bf7e-3b327afcb24e'	System	29 Aug 2020 06:59:41
User entered 'No (N)'	System	29 Aug 2020 06:59:41

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T23:59:38', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '9fa1afda-af78-45b3-bf7e-3b327afcb24e'	System	29 Aug 2020 06:59:41
User entered '28 Aug 2020 23:59'	System	29 Aug 2020 06:59:41

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 18:22'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 2'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:52:46', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '38d9367f-9c75-4fa1-a4e3-3dbfa600439a'	System	30 Aug 2020 05:53:29
User entered 'Yes (Y)'	System	30 Aug 2020 05:53:29

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:53:01', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '38d9367f-9c75-4fa1-a4e3-3dbfa600439a' User entered '100.8'	System	30 Aug 2020 05:53:29
	System	30 Aug 2020 05:53:29

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:53:06', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '38d9367f-9c75-4fa1-a4e3-3dbfa600439a'	System	30 Aug 2020 05:53:29
User entered 'Yes (Y)'	System	30 Aug 2020 05:53:29

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'per source documentation by previous crc subject did not report medication intake see source ' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 10:27:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Daisy Langarica (b) (4)	17 Dec 2020 18:45:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:53:18', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '38d9367f-9c75-4fa1-a4e3-3dbfa600439a'	(b) (4)	
User entered '1'	System	30 Aug 2020 05:53:29
	System	30 Aug 2020 05:53:29
	System	30 Aug 2020 05:53:29

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:53:18', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '38d9367f-9c75-4fa1-a4e3-3dbfa600439a' User entered '0'	System	30 Aug 2020 05:53:29
	System	30 Aug 2020 05:53:29

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:53:26', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '38d9367f-9c75-4fa1-a4e3-3dbfa600439a'	System	30 Aug 2020 05:53:29
User entered '29 Aug 2020 22:53'	System	30 Aug 2020 05:53:29

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 3'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:40:30', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6fc49c47-274d-4664-acb5-30c1e7ef95de'	System	31 Aug 2020 06:40:47
User entered 'Yes (Y)'	System	31 Aug 2020 06:40:47

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:40:36', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6fc49c47-274d-4664-acb5-30c1e7ef95de'	System	31 Aug 2020 06:40:47
User entered '99.2'	System	31 Aug 2020 06:40:47

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:40:40', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6fc49c47-274d-4664-acb5-30c1e7ef95de'	System	31 Aug 2020 06:40:47
User entered 'No (N)'	System	31 Aug 2020 06:40:47

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:40:44', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '6fc49c47-274d-4664-acb5-30c1e7ef95de'	System	31 Aug 2020 06:40:47
User entered '30 Aug 2020 23:40'	System	31 Aug 2020 06:40:47

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 4'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:34:40', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5dea5ebf-ca8d-4f1c-946a-c22824dc3af1'	System	31 Aug 2020 22:35:01
User entered 'Yes (Y)'	System	31 Aug 2020 22:35:01

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:34:49', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5dea5ebf-ca8d-4f1c-946a-c22824dc3af1' User entered '97.4'	System	31 Aug 2020 22:35:01
	System	31 Aug 2020 22:35:01

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:34:53', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5dea5ebf-ca8d-4f1c-946a-c22824dc3af1'	System	31 Aug 2020 22:35:01
User entered 'No (N)'	System	31 Aug 2020 22:35:01

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:34:58', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '5dea5ebf-ca8d-4f1c-946a-c22824dc3af1'	System	31 Aug 2020 22:35:01
User entered '31 Aug 2020 15:34'	System	31 Aug 2020 22:35:01

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 5'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:24:08', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'a58ae77e-c978-408a-bd14-96e93de028fa'	System	02 Sep 2020 00:24:31
User entered 'Yes (Y)'	System	02 Sep 2020 00:24:31

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:24:21', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'a58ae77e-c978-408a-bd14-96e93de028fa'	System	02 Sep 2020 00:24:31
User entered '98.8'	System	02 Sep 2020 00:24:31

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:24:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'a58ae77e-c978-408a-bd14-96e93de028fa'	System	02 Sep 2020 00:24:31
User entered 'No (N)'	System	02 Sep 2020 00:24:31

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:24:27', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'a58ae77e-c978-408a-bd14-96e93de028fa'	System	02 Sep 2020 00:24:31
User entered '01 Sep 2020 17:24'	System	02 Sep 2020 00:24:31

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 6'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:16:31', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '298a2b98-7b05-4152-aaa1-7c70ac4690d4'	System	03 Sep 2020 03:17:03
User entered 'Yes (Y)'	System	03 Sep 2020 03:17:03

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:16:40', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '298a2b98-7b05-4152-aaa1-7c70ac4690d4'	System	03 Sep 2020 03:17:03
User entered '98.1'	System	03 Sep 2020 03:17:03

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:16:43', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '298a2b98-7b05-4152-aaa1-7c70ac4690d4'	System	03 Sep 2020 03:17:03
User entered 'No (N)'	System	03 Sep 2020 03:17:03

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:16:57', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '298a2b98-7b05-4152-aaa1-7c70ac4690d4'	System	03 Sep 2020 03:17:03
User entered '02 Sep 2020 20:16'	System	03 Sep 2020 03:17:03

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 7'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:14:52', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'b7c0d28f-6c3a-45ac-9b7d-891bfa8fa2d7'	System	04 Sep 2020 02:15:10
User entered 'Yes (Y)'	System	04 Sep 2020 02:15:10

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'b7c0d28f-6c3a-45ac-9b7d-891bfa8fa2d7'	System	04 Sep 2020 02:15:10
User entered '98.1'	System	04 Sep 2020 02:15:10

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:04', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'b7c0d28f-6c3a-45ac-9b7d-891bfa8fa2d7'	System	04 Sep 2020 02:15:10
User entered 'No (N)'	System	04 Sep 2020 02:15:10

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:07', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'b7c0d28f-6c3a-45ac-9b7d-891bfa8fa2d7'	System	04 Sep 2020 02:15:10
User entered '03 Sep 2020 19:15'	System	04 Sep 2020 02:15:10

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:16', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e499b652-027b-4f9c-a3a1-abe423fa0b23'	System	28 Aug 2020 22:19:35
User entered 'None (1)'	System	28 Aug 2020 22:19:35

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:20', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e499b652-027b-4f9c-a3a1-abe423fa0b23'	System	28 Aug 2020 22:19:35
User entered 'No (N)'	System	28 Aug 2020 22:19:35

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e499b652-027b-4f9c-a3a1-abe423fa0b23'	System	28 Aug 2020 22:19:35
User entered 'No (N)'	System	28 Aug 2020 22:19:35

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:27', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e499b652-027b-4f9c-a3a1-abe423fa0b23'	System	28 Aug 2020 22:19:35
User entered 'None (1)'	System	28 Aug 2020 22:19:35

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:31', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e499b652-027b-4f9c-a3a1-abe423fa0b23'	System	28 Aug 2020 22:19:35
User entered '28 Aug 2020 15:19'	System	28 Aug 2020 22:19:35

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 14:57'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 17:27'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T23:59:52', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '82ad09e8-7765-4960-b334-21cce9ee002e'	System	29 Aug 2020 07:00:13
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 07:00:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T23:59:55', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '82ad09e8-7765-4960-b334-21cce9ee002e'	System	29 Aug 2020 07:00:13
User entered 'No (N)'	System	29 Aug 2020 07:00:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:04', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '82ad09e8-7765-4960-b334-21cce9ee002e'	System	29 Aug 2020 07:00:13
User entered 'No (N)'	System	29 Aug 2020 07:00:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:09', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '82ad09e8-7765-4960-b334-21cce9ee002e'	System	29 Aug 2020 07:00:13
User entered 'None (1)'	System	29 Aug 2020 07:00:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:12', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '82ad09e8-7765-4960-b334-21cce9ee002e'	System	29 Aug 2020 07:00:13
User entered '29 Aug 2020 00:00'	System	29 Aug 2020 07:00:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 18:22'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 2'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:53:37', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ffcc4165-5169-4e35-b86d-0784fa461053'	System	30 Aug 2020 05:54:47
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 05:54:47

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:54:12', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ffcc4165-5169-4e35-b86d-0784fa461053'	System	30 Aug 2020 05:54:47
User entered 'No (N)'	System	30 Aug 2020 05:54:47

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:54:16', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ffcc4165-5169-4e35-b86d-0784fa461053'	System	30 Aug 2020 05:54:47
User entered 'No (N)'	System	30 Aug 2020 05:54:47

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:54:35', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ffcc4165-5169-4e35-b86d-0784fa461053'	System	30 Aug 2020 05:54:47
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 05:54:47

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:54:45', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ffcc4165-5169-4e35-b86d-0784fa461053'	System	30 Aug 2020 05:54:47
User entered '29 Aug 2020 22:54'	System	30 Aug 2020 05:54:47

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 3'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:40:50', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7de95e50-ef9b-480a-b670-2b9b6e34a083'	System	31 Aug 2020 06:41:08
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 06:41:08

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:40:54', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7de95e50-ef9b-480a-b670-2b9b6e34a083'	System	31 Aug 2020 06:41:08
User entered 'No (N)'	System	31 Aug 2020 06:41:08

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:40:57', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7de95e50-ef9b-480a-b670-2b9b6e34a083'	System	31 Aug 2020 06:41:08
User entered 'No (N)'	System	31 Aug 2020 06:41:08

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:02', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7de95e50-ef9b-480a-b670-2b9b6e34a083'	System	31 Aug 2020 06:41:08
User entered 'None (1)'	System	31 Aug 2020 06:41:08

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:05', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7de95e50-ef9b-480a-b670-2b9b6e34a083'	System	31 Aug 2020 06:41:08
User entered '30 Aug 2020 23:41'	System	31 Aug 2020 06:41:08

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 4'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:05', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4b8bbc74-a82d-4d25-ad1b-a64aa54ded36'	System	31 Aug 2020 22:35:28
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 22:35:28

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:08', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4b8bbc74-a82d-4d25-ad1b-a64aa54ded36'	System	31 Aug 2020 22:35:28
User entered 'No (N)'	System	31 Aug 2020 22:35:28

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:12', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4b8bbc74-a82d-4d25-ad1b-a64aa54ded36'	System	31 Aug 2020 22:35:28
User entered 'No (N)'	System	31 Aug 2020 22:35:28

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4b8bbc74-a82d-4d25-ad1b-a64aa54ded36'	System	31 Aug 2020 22:35:28
User entered 'None (1)'	System	31 Aug 2020 22:35:28

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:26', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4b8bbc74-a82d-4d25-ad1b-a64aa54ded36'	System	31 Aug 2020 22:35:28
User entered '31 Aug 2020 15:35'	System	31 Aug 2020 22:35:28

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 5'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:24:40', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4c6b2854-d11f-4c8e-804d-6d1e115dbe18'	System	02 Sep 2020 00:25:04
User entered 'None (1)'	System	02 Sep 2020 00:25:04

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:24:43', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4c6b2854-d11f-4c8e-804d-6d1e115dbe18'	System	02 Sep 2020 00:25:04
User entered 'No (N)'	System	02 Sep 2020 00:25:04

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:24:52', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4c6b2854-d11f-4c8e-804d-6d1e115dbe18'	System	02 Sep 2020 00:25:04
User entered 'No (N)'	System	02 Sep 2020 00:25:04

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:24:56', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4c6b2854-d11f-4c8e-804d-6d1e115dbe18'	System	02 Sep 2020 00:25:04
User entered 'None (1)'	System	02 Sep 2020 00:25:04

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4c6b2854-d11f-4c8e-804d-6d1e115dbe18'	System	02 Sep 2020 00:25:04
User entered '01 Sep 2020 17:25'	System	02 Sep 2020 00:25:04

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 6'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:02', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'abda0fe9-f7e1-4305-86bf-abd26b307b5a'	System	03 Sep 2020 03:17:23
User entered 'None (1)'	System	03 Sep 2020 03:17:23

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:05', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'abda0fe9-f7e1-4305-86bf-abd26b307b5a'	System	03 Sep 2020 03:17:23
User entered 'No (N)'	System	03 Sep 2020 03:17:23

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:08', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'abda0fe9-f7e1-4305-86bf-abd26b307b5a'	System	03 Sep 2020 03:17:23
User entered 'No (N)'	System	03 Sep 2020 03:17:23

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:13', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'abda0fe9-f7e1-4305-86bf-abd26b307b5a'	System	03 Sep 2020 03:17:23
User entered 'None (1)'	System	03 Sep 2020 03:17:23

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:18', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'abda0fe9-f7e1-4305-86bf-abd26b307b5a'	System	03 Sep 2020 03:17:23
User entered '02 Sep 2020 20:17'	System	03 Sep 2020 03:17:23

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 7'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:11', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '92a55667-4f02-40a1-b243-7defde3bfe95'	System	04 Sep 2020 02:15:27
User entered 'None (1)'	System	04 Sep 2020 02:15:27

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:15', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '92a55667-4f02-40a1-b243-7defde3bfe95'	System	04 Sep 2020 02:15:27
User entered 'No (N)'	System	04 Sep 2020 02:15:27

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:18', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '92a55667-4f02-40a1-b243-7defde3bfe95'	System	04 Sep 2020 02:15:27
User entered 'No (N)'	System	04 Sep 2020 02:15:27

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:20', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '92a55667-4f02-40a1-b243-7defde3bfe95'	System	04 Sep 2020 02:15:27
User entered 'None (1)'	System	04 Sep 2020 02:15:27

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '92a55667-4f02-40a1-b243-7defde3bfe95'	System	04 Sep 2020 02:15:27
User entered '03 Sep 2020 19:15'	System	04 Sep 2020 02:15:27

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:39', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7814068d-5ba8-4acc-8b26-0b2344f41e80'	System	28 Aug 2020 22:20:17
User entered 'None (0)'	System	28 Aug 2020 22:20:17

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:46', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7814068d-5ba8-4acc-8b26-0b2344f41e80'	System	28 Aug 2020 22:20:17
User entered 'None (0)'	System	28 Aug 2020 22:20:17

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:50', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7814068d-5ba8-4acc-8b26-0b2344f41e80'	System	28 Aug 2020 22:20:17
User entered 'None (0)'	System	28 Aug 2020 22:20:17

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:54', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7814068d-5ba8-4acc-8b26-0b2344f41e80'	System	28 Aug 2020 22:20:17
User entered 'None (0)'	System	28 Aug 2020 22:20:17

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:19:58', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7814068d-5ba8-4acc-8b26-0b2344f41e80'	System	28 Aug 2020 22:20:17
User entered 'None (0)'	System	28 Aug 2020 22:20:17

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:20:02', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7814068d-5ba8-4acc-8b26-0b2344f41e80'	System	28 Aug 2020 22:20:17
User entered 'None (0)'	System	28 Aug 2020 22:20:17

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:20:09', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7814068d-5ba8-4acc-8b26-0b2344f41e80'	System	28 Aug 2020 22:20:17
User entered 'No (N)'	System	28 Aug 2020 22:20:17

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-28T15:20:14', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7814068d-5ba8-4acc-8b26-0b2344f41e80'	System	28 Aug 2020 22:20:17
User entered '28 Aug 2020 15:20'	System	28 Aug 2020 22:20:17

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 14:57'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 17:27'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:19', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '84516040-e2e4-43b9-9bef-e055fa61e2dd'	System	29 Aug 2020 07:00:56
User entered 'None (0)'	System	29 Aug 2020 07:00:56

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '84516040-e2e4-43b9-9bef-e055fa61e2dd'	System	29 Aug 2020 07:00:56
User entered 'None (0)'	System	29 Aug 2020 07:00:56

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:29', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '84516040-e2e4-43b9-9bef-e055fa61e2dd'	System	29 Aug 2020 07:00:56
User entered 'None (0)'	System	29 Aug 2020 07:00:56

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:32', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '84516040-e2e4-43b9-9bef-e055fa61e2dd'	System	29 Aug 2020 07:00:56
User entered 'None (0)'	System	29 Aug 2020 07:00:56

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:37', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '84516040-e2e4-43b9-9bef-e055fa61e2dd'	System	29 Aug 2020 07:00:56
User entered 'None (0)'	System	29 Aug 2020 07:00:56

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:41', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '84516040-e2e4-43b9-9bef-e055fa61e2dd'	System	29 Aug 2020 07:00:56
User entered 'None (0)'	System	29 Aug 2020 07:00:56

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:47', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '84516040-e2e4-43b9-9bef-e055fa61e2dd'	System	29 Aug 2020 07:00:56
User entered 'No (N)'	System	29 Aug 2020 07:00:56

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T00:00:51', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '84516040-e2e4-43b9-9bef-e055fa61e2dd'	System	29 Aug 2020 07:00:56
User entered '29 Aug 2020 00:00'	System	29 Aug 2020 07:00:56

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '28 Aug 2020 18:22'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 2'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:54:52', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ec20b63a-61c7-43b3-a51a-fff8d7ba3f0f'	System	30 Aug 2020 05:55:37
User entered 'None (0)'	System	30 Aug 2020 05:55:37

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:55:08', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ec20b63a-61c7-43b3-a51a-fff8d7ba3f0f'	System	30 Aug 2020 05:55:37
User entered 'Some interference with activity (2)'	System	30 Aug 2020 05:55:37

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:55:11', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ec20b63a-61c7-43b3-a51a-fff8d7ba3f0f'	System	30 Aug 2020 05:55:37
User entered 'None (0)'	System	30 Aug 2020 05:55:37

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:55:14', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ec20b63a-61c7-43b3-a51a-fff8d7ba3f0f'	System	30 Aug 2020 05:55:37
User entered 'None (0)'	System	30 Aug 2020 05:55:37

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:55:19', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ec20b63a-61c7-43b3-a51a-fff8d7ba3f0f'	System	30 Aug 2020 05:55:37
User entered 'None (0)'	System	30 Aug 2020 05:55:37

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:55:28', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ec20b63a-61c7-43b3-a51a-fff8d7ba3f0f'	System	30 Aug 2020 05:55:37
User entered 'No interference with activity (1)'	System	30 Aug 2020 05:55:37

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:55:32', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ec20b63a-61c7-43b3-a51a-fff8d7ba3f0f'	System	30 Aug 2020 05:55:37
User entered 'No (N)'	System	30 Aug 2020 05:55:37

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-29T22:55:35', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'ec20b63a-61c7-43b3-a51a-fff8d7ba3f0f'	System	30 Aug 2020 05:55:37
User entered '29 Aug 2020 22:55'	System	30 Aug 2020 05:55:37

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 3'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:12', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '506e3dcc-45ed-4cfd-87b3-7aae8bfc82fd'	System	31 Aug 2020 06:41:38
User entered 'None (0)'	System	31 Aug 2020 06:41:38

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:17', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '506e3dcc-45ed-4cf8-87b3-7aae8bfc82fd'	System	31 Aug 2020 06:41:38
User entered 'None (0)'	System	31 Aug 2020 06:41:38

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:20', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '506e3dcc-45ed-4cf8-87b3-7aae8bfc82fd'	System	31 Aug 2020 06:41:38
User entered 'None (0)'	System	31 Aug 2020 06:41:38

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '506e3dcc-45ed-4cfd-87b3-7aae8bfc82fd'	System	31 Aug 2020 06:41:38
User entered 'None (0)'	System	31 Aug 2020 06:41:38

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:26', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '506e3dcc-45ed-4cfd-87b3-7aae8bfc82fd'	System	31 Aug 2020 06:41:38
User entered 'None (0)'	System	31 Aug 2020 06:41:38

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:29', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '506e3dcc-45ed-4cf8-87b3-7aae8bfc82fd'	System	31 Aug 2020 06:41:38
User entered 'None (0)'	System	31 Aug 2020 06:41:38

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:34', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '506e3dcc-45ed-4cfd-87b3-7aae8bfc82fd'	System	31 Aug 2020 06:41:38
User entered 'No (N)'	System	31 Aug 2020 06:41:38

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-30T23:41:37', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '506e3dcc-45ed-4cfd-87b3-7aae8bfc82fd'	System	31 Aug 2020 06:41:38
User entered '30 Aug 2020 23:41'	System	31 Aug 2020 06:41:38

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 4'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:33', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73c6936f-6663-443c-9155-a4c09b450d9c'	System	31 Aug 2020 22:36:12
User entered 'None (0)'	System	31 Aug 2020 22:36:12

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:46', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73c6936f-6663-443c-9155-a4c09b450d9c'	System	31 Aug 2020 22:36:12
User entered 'No interference with activity (1)'	System	31 Aug 2020 22:36:12

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:49', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73c6936f-6663-443c-9155-a4c09b450d9c'	System	31 Aug 2020 22:36:12
User entered 'None (0)'	System	31 Aug 2020 22:36:12

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:52', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73c6936f-6663-443c-9155-a4c09b450d9c'	System	31 Aug 2020 22:36:12
User entered 'None (0)'	System	31 Aug 2020 22:36:12

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:55', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73c6936f-6663-443c-9155-a4c09b450d9c'	System	31 Aug 2020 22:36:12
User entered 'None (0)'	System	31 Aug 2020 22:36:12

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:35:57', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73c6936f-6663-443c-9155-a4c09b450d9c'	System	31 Aug 2020 22:36:12
User entered 'None (0)'	System	31 Aug 2020 22:36:12

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:36:01', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73c6936f-6663-443c-9155-a4c09b450d9c'	System	31 Aug 2020 22:36:12
User entered 'No (N)'	System	31 Aug 2020 22:36:12

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-08-31T15:36:09', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '73c6936f-6663-443c-9155-a4c09b450d9c'	System	31 Aug 2020 22:36:12
User entered '31 Aug 2020 15:36'	System	31 Aug 2020 22:36:12

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 5'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:10', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9e49912-d366-495f-8f26-dbfdd10a571d'	System	02 Sep 2020 00:25:51
User entered 'None (0)'	System	02 Sep 2020 00:25:51

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:14', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9e49912-d366-495f-8f26-dbfdd10a571d'	System	02 Sep 2020 00:25:51
User entered 'None (0)'	System	02 Sep 2020 00:25:51

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:18', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9e49912-d366-495f-8f26-dbfdd10a571d' User entered 'None (0)'	System	02 Sep 2020 00:25:51
	System	02 Sep 2020 00:25:51

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:22', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9e49912-d366-495f-8f26-dbfdd10a571d'	System	02 Sep 2020 00:25:51
User entered 'None (0)'	System	02 Sep 2020 00:25:51

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9e49912-d366-495f-8f26-dbfdd10a571d'	System	02 Sep 2020 00:25:51
User entered 'None (0)'	System	02 Sep 2020 00:25:51

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:31', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9e49912-d366-495f-8f26-dbfdd10a571d'	System	02 Sep 2020 00:25:51
User entered 'None (0)'	System	02 Sep 2020 00:25:51

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:44', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9e49912-d366-495f-8f26-dbfdd10a571d'	System	02 Sep 2020 00:25:51
User entered 'No (N)'	System	02 Sep 2020 00:25:51

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-01T17:25:47', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'f9e49912-d366-495f-8f26-dbfdd10a571d'	System	02 Sep 2020 00:25:51
User entered '01 Sep 2020 17:25'	System	02 Sep 2020 00:25:51

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 6'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d9c5982-53c8-4fae-b098-b2e5a2f41b6f'	System	03 Sep 2020 03:17:59
User entered 'None (0)'	System	03 Sep 2020 03:17:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:26', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d9c5982-53c8-4fae-b098-b2e5a2f41b6f'	System	03 Sep 2020 03:17:59
User entered 'None (0)'	System	03 Sep 2020 03:17:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:28', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d9c5982-53c8-4fae-b098-b2e5a2f41b6f'	System	03 Sep 2020 03:17:59
User entered 'None (0)'	System	03 Sep 2020 03:17:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:31', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d9c5982-53c8-4fae-b098-b2e5a2f41b6f'	System	03 Sep 2020 03:17:59
User entered 'None (0)'	System	03 Sep 2020 03:17:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:33', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d9c5982-53c8-4fae-b098-b2e5a2f41b6f'	System	03 Sep 2020 03:17:59
User entered 'None (0)'	System	03 Sep 2020 03:17:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:36', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d9c5982-53c8-4fae-b098-b2e5a2f41b6f'	System	03 Sep 2020 03:17:59
User entered 'None (0)'	System	03 Sep 2020 03:17:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:48', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d9c5982-53c8-4fae-b098-b2e5a2f41b6f'	System	03 Sep 2020 03:17:59
User entered 'No (N)'	System	03 Sep 2020 03:17:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-02T20:17:54', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d9c5982-53c8-4fae-b098-b2e5a2f41b6f'	System	03 Sep 2020 03:17:59
User entered '02 Sep 2020 20:17'	System	03 Sep 2020 03:17:59

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	28 Aug 2020 22:14:13
User entered 'Day 7'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:28', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8ad5a0f3-9470-48aa-8787-c0ff927ff0dc'	System	04 Sep 2020 02:15:54
User entered 'None (0)'	System	04 Sep 2020 02:15:54

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:37', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8ad5a0f3-9470-48aa-8787-c0ff927ff0dc'	System	04 Sep 2020 02:15:54
User entered 'None (0)'	System	04 Sep 2020 02:15:54

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:39', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8ad5a0f3-9470-48aa-8787-c0ff927ff0dc'	System	04 Sep 2020 02:15:54
User entered 'None (0)'	System	04 Sep 2020 02:15:54

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:41', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8ad5a0f3-9470-48aa-8787-c0ff927ff0dc'	System	04 Sep 2020 02:15:54
User entered 'None (0)'	System	04 Sep 2020 02:15:54

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:42', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8ad5a0f3-9470-48aa-8787-c0ff927ff0dc'	System	04 Sep 2020 02:15:54
User entered 'None (0)'	System	04 Sep 2020 02:15:54

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:45', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8ad5a0f3-9470-48aa-8787-c0ff927ff0dc'	System	04 Sep 2020 02:15:54
User entered 'None (0)'	System	04 Sep 2020 02:15:54

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:48', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8ad5a0f3-9470-48aa-8787-c0ff927ff0dc'	System	04 Sep 2020 02:15:54
User entered 'No (N)'	System	04 Sep 2020 02:15:54

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-03T19:15:50', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '8ad5a0f3-9470-48aa-8787-c0ff927ff0dc'	System	04 Sep 2020 02:15:54
User entered '03 Sep 2020 19:15'	System	04 Sep 2020 02:15:54

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:14:13

US3262055

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:15:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:14:13

US3262055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:18
User entered 'Yes (Y)'		15 Oct 2020 18:34:51

US3262055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:18
User entered '04 Sep 2020'		15 Oct 2020 18:34:51

US3262055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:18
User entered 'Contact Made (CONTACT MADE)'		15 Oct 2020 18:34:51

US3262055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:18
User entered empty.		15 Oct 2020 18:34:51

US3262055

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:56
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:19:34

US3262055

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'I'	System	29 Sep 2020 01:19:34

US3262055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:43:23
User entered 'Yes (Y)'		15 Oct 2020 18:35:07

US3262055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:43:23
User entered '11 Sep 2020'		15 Oct 2020 18:35:07

US3262055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:43:23
User entered 'Contact Made (CONTACT MADE)'		15 Oct 2020 18:35:07

US3262055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:43:23
User entered empty.		15 Oct 2020 18:35:07

US3262055

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:44:18
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:20:07

US3262055

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'I'	System	29 Sep 2020 01:20:07

US3262055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:44:34
User entered 'Yes (Y)'		15 Oct 2020 18:35:28

US3262055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:44:34
User entered '18 Sep 2020'		15 Oct 2020 18:35:28

US3262055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:44:34
User entered 'Contact Made (CONTACT MADE)'		15 Oct 2020 18:35:28

US3262055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:44:34
User entered empty.		15 Oct 2020 18:35:28

US3262055

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:14
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:20:16

US3262055

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'I'	System	29 Sep 2020 01:20:16

US3262055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:00:50
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:20:45

US3262055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 17:00:50
User entered '25 Sep 2020'	Alia Bober (b) (4)	29 Sep 2020 01:20:45

US3262055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:00:50
User entered 'Clinic (Clinic)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:20:45

US3262055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'VISIT3'	System	29 Sep 2020 01:20:45

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered '25 Sep 2020'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered '12:45'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '25 Sep 2020 12:45'	System	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered '98.4' F	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered 'Oral (Oral)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered empty.	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered '70'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'bpm'	System	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered '14'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'breaths/min'	System	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4)	15 Oct 2020 17:01:00
User entered '116'	(b) (4), (b) (6)	15 Oct 2020 17:01:00
	Alia Bober (b) (4)	29 Sep 2020 01:21:24
	(b) (4)	

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'mmHg'	System	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:00
User entered '71'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'mmHg'	System	29 Sep 2020 01:21:24

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48

US3262055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48

US3262055

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
Data hard locked.	(b) (4)	27 Apr 2021 16:14:48
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:38:55
User closed query 'Per the source documents a physical exam was not completed. Please confirm and update.' (Site from CRA).		08 Apr 2021 18:38:49
Query 'Per the source documents a physical exam was not completed. Please confirm and update.' answered with 'UPDATED ' (Site from CRA).	Daisy Langarica (b) (4)	08 Apr 2021 17:47:38
Signature has been broken.	(b) (4)	
	Daisy Langarica (b) (4)	08 Apr 2021 17:47:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 17:47:19
User opened query 'Per the source documents a physical exam was not completed. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 22:03:58
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered 'Yes (Y)'	(b) (4)	
	Alia Bober (b) (4)	29 Sep 2020 01:21:41
	(b) (4)	

US3262055

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 16:14:48
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:38:55
Signature has been broken.	Daisy Langarica (b) (4)	08 Apr 2021 17:47:19
	(b) (4)	
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4)	08 Apr 2021 17:47:19
	(b) (4)	
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
	(b) (4)	
User entered '25 Sep 2020'	Alia Bober (b) (4)	29 Sep 2020 01:21:41
	(b) (4)	

US3262055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:38
User entered 'Yes (Y)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:22:00

US3262055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:38
User entered '25 Sep 2020'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:22:00

US3262055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:38
User entered '13:02'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:22:00

US3262055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '25 Sep 2020 13:02'	System	29 Sep 2020 01:22:00

US3262055

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
DataPoint Verified.		06 Apr 2021 22:00:57
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:28:59
User entered 'Yes (Y)'	(b) (4) Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:22:06

US3262055

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered '1'	System	29 Sep 2020 01:22:06

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 64'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-30T15:48:34', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e3ff95b8-c792-401e-bde2-8ffbdfe067cc'	System	30 Sep 2020 22:48:54
User entered 'No (N)'	System	30 Sep 2020 22:48:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-30T15:48:41', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e3ff95b8-c792-401e-bde2-8ffbdfe067cc'	System	30 Sep 2020 22:48:54
User entered 'No (N)'	System	30 Sep 2020 22:48:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-09-30T15:48:50', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e3ff95b8-c792-401e-bde2-8ffbdfe067cc'	System	30 Sep 2020 22:48:54
User entered '30 Sep 2020 15:48:50'	System	30 Sep 2020 22:48:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '29 Sep 2020 00:01'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '03 Oct 2020 23:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 71'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-07T07:12:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '1ce13c65-4936-4a11-9bd2-df2dc6b3fd91'	System	07 Oct 2020 14:12:43
User entered 'No (N)'	System	07 Oct 2020 14:12:43

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-07T07:12:13', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '1ce13c65-4936-4a11-9bd2-df2dc6b3fd91'	System	07 Oct 2020 14:12:43
User entered 'No (N)'	System	07 Oct 2020 14:12:43

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-07T07:12:39', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '1ce13c65-4936-4a11-9bd2-df2dc6b3fd91'	System	07 Oct 2020 14:12:43
User entered '07 Oct 2020 07:12:39'	System	07 Oct 2020 14:12:43

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '06 Oct 2020 00:01'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '10 Oct 2020 23:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 78'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 12:37:39
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'per source note subject did not report any signs/symptoms of COVID ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 21:11:28
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:59:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-17T12:00:35', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7cd9b6af-1fe4-45c4-ac1b-31dcb82f649c'	System	17 Oct 2020 19:01:47
User entered 'Yes (Y)'	System	17 Oct 2020 19:01:47

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-17T12:00:46', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7cd9b6af-1fe4-45c4-ac1b-31dcb82f649c'	System	17 Oct 2020 19:01:47
User entered 'No (N)'	System	17 Oct 2020 19:01:47

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-17T12:00:53', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7cd9b6af-1fe4-45c4-ac1b-31dcb82f649c'	System	17 Oct 2020 19:01:47
User entered 'No (N)'	System	17 Oct 2020 19:01:47

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-17T12:01:02', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7cd9b6af-1fe4-45c4-ac1b-31dcb82f649c'	System	17 Oct 2020 19:01:47
User entered 'Yes (Y)'	System	17 Oct 2020 19:01:47

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-17T12:01:25', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7cd9b6af-1fe4-45c4-ac1b-31dcb82f649c'	System	17 Oct 2020 19:01:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Oct 2020 19:01:47

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-10-17T12:01:36', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '7cd9b6af-1fe4-45c4-ac1b-31dcb82f649c'	System	17 Oct 2020 19:01:47
User entered '17 Oct 2020 12:01:36'	System	17 Oct 2020 19:01:47

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '13 Oct 2020 00:01'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '17 Oct 2020 23:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 92'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '27 Oct 2020 00:01'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:45:41
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '31 Oct 2020 23:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 99'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-04T09:25:34', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05536f7c-3a6d-4c5a-af79-2461725ea686'	System	04 Nov 2020 17:25:57
User entered 'No (N)'	System	04 Nov 2020 17:25:57

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-04T09:25:44', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05536f7c-3a6d-4c5a-af79-2461725ea686'	System	04 Nov 2020 17:25:57
User entered 'No (N)'	System	04 Nov 2020 17:25:57

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-04T09:25:53', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '05536f7c-3a6d-4c5a-af79-2461725ea686'	System	04 Nov 2020 17:25:57
User entered '04 Nov 2020 09:25:53'	System	04 Nov 2020 17:25:57

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '03 Nov 2020 00:01'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '07 Nov 2020 23:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 106'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-10T15:18:53', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'd7c83c03-52c2-4b9a-a3d1-9d0fe54190c0'	System	10 Nov 2020 23:19:07
User entered 'No (N)'	System	10 Nov 2020 23:19:07

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-10T15:18:57', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'd7c83c03-52c2-4b9a-a3d1-9d0fe54190c0'	System	10 Nov 2020 23:19:07
User entered 'No (N)'	System	10 Nov 2020 23:19:07

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-10T15:19:03', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'd7c83c03-52c2-4b9a-a3d1-9d0fe54190c0'	System	10 Nov 2020 23:19:07
User entered '10 Nov 2020 15:19:03'	System	10 Nov 2020 23:19:07

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '10 Nov 2020 00:01'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '14 Nov 2020 23:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered 'Day 113'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-17T09:09:46', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '1bbd8e8c-18ec-48d6-8fc0-54f5f6a88dcf'	System	17 Nov 2020 17:10:01
User entered 'No (N)'	System	17 Nov 2020 17:10:01

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-17T09:09:51', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '1bbd8e8c-18ec-48d6-8fc0-54f5f6a88dcf'	System	17 Nov 2020 17:10:01
User entered 'No (N)'	System	17 Nov 2020 17:10:01

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-17T09:09:56', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '1bbd8e8c-18ec-48d6-8fc0-54f5f6a88dcf'	System	17 Nov 2020 17:10:01
User entered '17 Nov 2020 09:09:56'	System	17 Nov 2020 17:10:01

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '17 Nov 2020 00:01'	System	30 Jul 2020 22:10:54

US3262055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:47:38
Data entry locked.	System	30 Jul 2020 22:10:54
User entered '21 Nov 2020 23:59'	System	30 Jul 2020 22:10:54

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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 (61ef3ed3bf968e45)', Time: '2020-11-30T19:08:23', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '971562b9-7f12-4a19-ac94-0a8b3cdb7e20'	System	01 Dec 2020 03:08:43
User entered 'No (N)'	System	01 Dec 2020 03:08:43

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with 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 (61ef3ed3bf968e45)', Time: '2020-11-30T19:08:32', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '971562b9-7f12-4a19-ac94-0a8b3cdb7e20'	System	01 Dec 2020 03:08:43
User entered 'No (N)'	System	01 Dec 2020 03:08:43

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-11-30T19:08:40', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '971562b9-7f12-4a19-ac94-0a8b3cdb7e20'	System	01 Dec 2020 03:08:43
User entered '30 Nov 2020 19:08:40'	System	01 Dec 2020 03:08:43

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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 (61ef3ed3bf968e45)', Time: '2020-12-05T14:00:34', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4002f97b-6ddd-4c03-85d6-be7fdf4ae113'	System	05 Dec 2020 22:00:48
User entered 'No (N)'	System	05 Dec 2020 22:00:48

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with 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 (61ef3ed3bf968e45)', Time: '2020-12-05T14:00:42', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4002f97b-6ddd-4c03-85d6-be7fdf4ae113'	System	05 Dec 2020 22:00:48
User entered 'No (N)'	System	05 Dec 2020 22:00:48

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2020-12-05T14:00:45', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4002f97b-6ddd-4c03-85d6-be7fdf4ae113'	System	05 Dec 2020 22:00:48
User entered '05 Dec 2020 14:00:45'	System	05 Dec 2020 22:00:48

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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 (61ef3ed3bf968e45)', Time: '2021-03-17T17:11:51-07:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e4b2fe16-eb77-46f8-b39d-a5905ce755e1'	System	18 Mar 2021 00:12:13
User entered 'No (N)'	System	18 Mar 2021 00:12:13

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with 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 (61ef3ed3bf968e45)', Time: '2021-03-17T17:12:00-07:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e4b2fe16-eb77-46f8-b39d-a5905ce755e1'	System	18 Mar 2021 00:12:13
User entered 'No (N)'	System	18 Mar 2021 00:12:13

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2021-03-17T17:12:08-07:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: 'e4b2fe16-eb77-46f8-b39d-a5905ce755e1' User entered '17 Mar 2021 17:12:08'	System	18 Mar 2021 00:12:13
	System	18 Mar 2021 00:12:13

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[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 (61ef3ed3bf968e45)', Time: '2021-04-21T13:51:06-07:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '54dd6b0a-b367-4251-bf64-9751db32855f'	System	21 Apr 2021 20:51:45
User entered 'Yes (Y)'	System	21 Apr 2021 20:51:45

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

Have you been exposed to someone with 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 (61ef3ed3bf968e45)', Time: '2021-04-21T13:51:14-07:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '54dd6b0a-b367-4251-bf64-9751db32855f'	System	21 Apr 2021 20:51:45
User entered 'No (N)'	System	21 Apr 2021 20:51:45

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2021-04-21T13:51:20-07:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '54dd6b0a-b367-4251-bf64-9751db32855f'	System	21 Apr 2021 20:51:45
User entered 'No (N)'	System	21 Apr 2021 20:51:45

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2021-04-21T13:51:32-07:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '54dd6b0a-b367-4251-bf64-9751db32855f' User entered 'No (N)'	System	21 Apr 2021 20:51:45
	System	21 Apr 2021 20:51:45

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2021-04-21T13:51:42-07:00', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '54dd6b0a-b367-4251-bf64-9751db32855f' User entered '21 Apr 2021 13:51:42'	System	21 Apr 2021 20:51:45
	System	21 Apr 2021 20:51:45

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 10:45:41

US3262055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:45:41
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 10:45:41

US3262055

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:15:52

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)	25 Apr 2021 08:48:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2021-03-12T17:05:38', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d8b05da-8534-4697-80b9-1bf0ff37f350'	System	13 Mar 2021 01:05:47
User entered 'No (N)'	System	13 Mar 2021 01:05:47

US3262055

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:15:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:48:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61ef3ed3bf968e45)', Time: '2021-03-12T17:05:42', User OID: 'PatientReportedOutcome (US3262055)', ODM File OID: '4d8b05da-8534-4697-80b9-1bf0ff37f350'	System	13 Mar 2021 01:05:47
User entered '12 Mar 2021 17:05:42'	System	13 Mar 2021 01:05:47

US3262055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:32:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:48:08
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:18

US3262055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:32:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:48:08
User entered '23 Oct 2020'	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:18

US3262055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:32:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:48:08
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:18

US3262055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:32:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:48:08
User entered empty.	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:18

US3262055

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:32:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:48:16
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:25

US3262055

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:14:48
User entered 'I'	System	02 Dec 2020 18:35:25

US3262055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:52:41
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:34

US3262055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:52:41
User entered '30 Nov 2020'	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:34

US3262055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:52:41
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:34

US3262055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:52:41
User entered empty.	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:34

US3262055

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:52:47
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	02 Dec 2020 18:35:38

US3262055

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:38
User entered 'I'	System	02 Dec 2020 18:35:38

US3262055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:53:16
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	29 Dec 2020 01:09:17

US3262055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:53:16
User entered '28 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	29 Dec 2020 01:09:17

US3262055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:53:16
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	29 Dec 2020 01:09:17

US3262055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:53:16
User entered empty.	Daisy Langarica (b) (4) (b) (4)	29 Dec 2020 01:09:17

US3262055

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	17 Mar 2021 16:53:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	29 Dec 2020 01:09:01

US3262055

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:38
User entered 'I'	System	29 Dec 2020 01:09:01

US3262055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:22:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 17:41:53

US3262055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:22:14
User entered '26 Jan 2021'		29 Jan 2021 17:41:53

US3262055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:22:14
User entered 'Contact Made (CONTACT MADE)'		29 Jan 2021 17:41:53

US3262055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:22:14
User entered empty.		29 Jan 2021 17:41:53

US3262055

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:34:31
User entered 'Yes (Y)'		29 Jan 2021 17:41:58

US3262055

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:38
User entered 'I'	System	29 Jan 2021 17:41:58

US3262055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:53:35
User entered 'Yes (Y)'		25 Feb 2021 21:25:23

US3262055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:53:35
User entered '25 Feb 2021'		25 Feb 2021 21:25:23

US3262055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:53:35
User entered 'Clinic (Clinic)'		25 Feb 2021 21:25:23

US3262055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered 'VISIT4'	System	25 Feb 2021 21:25:23

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered '25 Feb 2021'	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered '12:55'	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered '25 Feb 2021 12:55'	System	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered '98.0' F	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered 'Oral (Oral)'	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered empty.	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered '82'	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered 'bpm'	System	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered '15'	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered 'breaths/min'	System	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
User entered '96'	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered 'mmHg'	System	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:03:06
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).		02 Apr 2021 16:21:24
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' (Site from System).		01 Apr 2021 23:24:28
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).		31 Mar 2021 23:16:18
User entered '51'	Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered 'mmHg'	System	31 Mar 2021 23:16:18

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00

US3262055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00

US3262055

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:11:23
User entered 'No (N)'		25 Feb 2021 21:25:29

US3262055

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:11:23
User entered empty.		25 Feb 2021 21:25:29

US3262055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:11:32
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	05 Mar 2021 02:02:07

US3262055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:11:32
User entered '25 Feb 2021'	Atoya Adams (b) (4) (b) (4)	05 Mar 2021 02:02:07

US3262055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:11:32
User entered '13:04'	Atoya Adams (b) (4) (b) (4)	05 Mar 2021 02:02:07

US3262055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered '25 Feb 2021 13:04'	System	05 Mar 2021 02:02:07

US3262055

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:12:05
User entered 'Yes (Y)'		25 Feb 2021 21:25:33

US3262055

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered 'I'	System	25 Feb 2021 21:25:33

US3262055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	28 Apr 2021 21:49:29
	(b) (4)	

US3262055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	28 Apr 2021 21:49:33
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	28 Apr 2021 21:49:33
User entered '28 Mar 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	28 Apr 2021 21:49:33
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Apr 2021 21:49:29
User entered '28 Apr 2021'	Daisy Langarica (b) (4) (b) (4)	28 Apr 2021 21:49:29

US3262055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	28 Apr 2021 21:49:29

US3262055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	28 Apr 2021 21:49:29
	(b) (4)	

US3262055

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	28 Apr 2021 21:49:37
	(b) (4)	

US3262055

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 21:49:37

US3262055

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	28 Apr 2021 21:49:48
	(b) (4)	

US3262055

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
	(b) (4)	
User entered '28 Apr 2021'	Daisy Langarica (b) (4)	28 Apr 2021 21:49:48
	(b) (4)	

US3262055

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	28 Apr 2021 21:49:48

US3262055

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	28 Apr 2021 21:49:48
	(b) (4)	

US3262055

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:42
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	28 Apr 2021 21:50:04
	(b) (4)	

US3262055

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 21:50:04

US3262055

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

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:16:10
User entered 'Yes (Y)'		10 Mar 2021 18:54:53

US3262055

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

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:16:10
User entered '10 Mar 2021'		10 Mar 2021 18:54:53

US3262055

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

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:16:10
User entered 'Clinic (Clinic)'		10 Mar 2021 18:54:53

US3262055

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

Form: Visit Date

Generated On: 09 Jun 2021 16:15:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered 'UNBLND_DECIDE'	System	10 Mar 2021 18:54:53

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered '10 Mar 2021'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered '0'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered 'Yes (Y)'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered 'Amendment 6 or later (Amendment 6 or later)'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered '10 Mar 2021'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered 'mRNA-1273 (mRNA-1273)'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered 'mRNA-1273 (mRNA-1273)'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered 'mRNA-1273 (mRNA-1273)'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:22:04
User entered 'No (N)'		10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered empty.	System	10 Mar 2021 18:55:35

US3262055

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

Form: Unblinding

Generated On: 09 Jun 2021 16:15:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered empty.	System	10 Mar 2021 18:55:35

US3262055

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:28
User entered 'Yes (Y)'		10 Mar 2021 18:57:34

US3262055

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:28
User entered '10 Mar 2021'		10 Mar 2021 18:57:34

US3262055

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:28
User entered '10:19'		10 Mar 2021 18:57:34

US3262055

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered '10 Mar 2021 10:19'	System	10 Mar 2021 18:57:34

US3262055

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:35
User entered 'Yes (Y)'		10 Mar 2021 18:57:43

US3262055

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:35
User entered '10 Mar 2021'		10 Mar 2021 18:57:43

US3262055

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:23:35
User entered '10:22'		10 Mar 2021 18:57:43

US3262055

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:52

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:20:00
User entered '10 Mar 2021 10:22'	System	10 Mar 2021 18:57:43

US3262055

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:15:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:15
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:27:51
User entered 'Yes (Y)' reason for change: New Information		25 Feb 2021 21:25:46
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	29 Sep 2020 01:22:18

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 15:56:42
User entered 'USA-US069-2021-mRNA-1273-P301000001'	System	26 Feb 2021 15:56:31
User entered 'New'	(b) (4), (b) (6)	26 Feb 2021 15:56:31

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query 'Per DM CLR: Please review and specify which "SEQUELAE." Update and reconcile with Con Med eCRF as appropriate. Otherwise, clarify. ' (Site from DM).		25 Mar 2021 09:20:50
Query 'Per DM CLR: Please review and specify which "SEQUELAE." Update and reconcile with Con Med eCRF as appropriate. Otherwise, clarify. ' answered with 'sequelae means consequence of having metastatic malignancy of unknown origin. any symptoms the patient has had is from the malignancy' (Site from DM).	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:39:52
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Metastatic neoplasm, LLT: Metastatic neoplasm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 14:08:33
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 14:08:33
User opened query 'Per DM CLR: Please review and specify which "SEQUELAE." Update and reconcile with Con Med eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:03:16
Data point term sent to Coder	System	25 Feb 2021 21:29:54
User entered 'Sequelae from metastatic malignancy of unknown origin'	(b) (4), (b) (6)	25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Yes (Y)'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'No (N)'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'No (N)'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '5 Feb 2021'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Yes (Y)'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		11 Mar 2021 18:06:32
Query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing' (Site from Safety).		10 Mar 2021 21:13:16
User opened query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		03 Mar 2021 19:14:35
User entered empty.		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Grade 3/Severe (Grade 3/Severe)'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Yes (Y)'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '1'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '05 Feb 2021'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 15:34:00
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'discharge summary faxed and emailed 4/13/2021' (Site from Safety).		13 Apr 2021 17:08:02
DataPoint Verified.		06 Apr 2021 22:43:32
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		03 Mar 2021 21:20:08
User entered '11 Feb 2021'		25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	25 Feb 2021 21:29:39
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		25 Feb 2021 21:29:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:29:39
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	25 Feb 2021 21:29:03
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'		25 Feb 2021 21:29:03

US3262055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).		25 Mar 2021 14:17:55
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'corrected as per query' (Site from Safety).	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:42:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:40:59
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:42:41
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).		25 Mar 2021 14:17:57
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' answered with 'corrected' (Site from Safety).	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:42:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:40:59
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:43:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		11 Mar 2021 18:06:42
Query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).		10 Mar 2021 21:15:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution		10 Mar 2021 21:14:36
User opened query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		03 Mar 2021 19:13:45
User entered 'None (NONE)'		25 Feb 2021 21:29:03

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'		25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		03 Mar 2021 19:14:04
User entered 'I'		25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'		25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).		25 Mar 2021 14:18:06
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'They still don't know the origin of this and all tests have been negative so far. They are still investigating and patient is seeking other opinions' (Site from Safety).	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:44:29
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 19:14:50
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:29:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 21:29:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:29:39
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:29:03
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:29:03

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.		25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		25 Mar 2021 14:18:55
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event' (Site from Safety).		25 Mar 2021 14:18:16
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'All tests were within normal limits, which is why all are so puzzled. Nothing can be found to explain, and all tests, including blood tests for tumor markers have been negative.' (Site from Safety).	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:47:25
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event' answered with 'None. plus, without knowing definitively what the patient has, one cannot say. But patient has no known risk factors for malignancy that they are aware of, which is why this is so puzzling.' (Site from Safety).	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:46:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 19:15:33
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event' (Site from Safety).		03 Mar 2021 19:14:19

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Mar 2021 17:02:47
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	01 Mar 2021 17:02:47
User entered 'patient presented to hospital due to sequelae from metastatic malignancy of unknown origin. They are actively looking for a malignancy source, but all tests have come back negative.' reason for change: New Information	Atoya Adams (b) (4) (b) (4)	01 Mar 2021 17:02:47
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 21:29:03
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 21:29:03

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: Appetite disorders, PT: Decreased appetite, LLT: Decreased appetite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:52:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:52:38
Data point term sent to Coder	System	24 Mar 2021 18:51:26
User entered 'Decreased Appetite'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '10 Feb 2021'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Mar 2021 18:55:44
User entered empty; reason for change Data Entry Error	Atoya Adams (b) (4)	24 Mar 2021 18:55:44
User entered '14:00' reason for change: Data Entry Error	Atoya Adams (b) (4)	24 Mar 2021 18:55:16
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Mar 2021 18:51:01
User entered '08:00'	Atoya Adams (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 18:55:44
User entered '10 Feb 2021 14:00'	System	24 Mar 2021 18:55:16
User entered '10 Feb 2021 08:00'	System	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Not Related (NOT RELATED)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Not Related (NOT RELATED)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'None (NONE)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'I'	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered '0'	Atoya Adams (b) (4)	24 Mar 2021 18:51:01
	(b) (4)	

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:43:32
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:51:01

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 18:51:01

US3262055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 18:51:01

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:15
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:35:55
DataPoint Un-verified.		25 Feb 2021 21:33:26
User entered 'Yes (Y)' reason for change: Data Entry Error		25 Feb 2021 21:33:26
DataPoint Verified.		30 Sep 2020 18:26:56
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:39

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: APPETITE STIMULANTS, PRODUCT: MEGESTROL ACETATE, PRODUCTSYNONYM: MEGASTROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 05:28:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 05:28:32
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
Data point term sent to Coder	System (b) (4)	08 Apr 2021 17:44:34
Coding entries removed.	Daisy Langarica (b) (4)	08 Apr 2021 17:44:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:36:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: APPETITE STIMULANTS, PRODUCT: MEGESTROL ACETATE, PRODUCTSYNONYM: MEGASTROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 12:08:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 12:08:49
Data point term sent to Coder	System	25 Feb 2021 21:35:59
User entered 'Megastrol'	(b) (4), (b) (6)	25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:36:51
User entered 'No (N)'		25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:04:22
User closed query 'Per DM CLR-RQ: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (e.g. Decreased Appetite). Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4)	09 Apr 2021 14:22:10
Query 'Per DM CLR-RQ: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (e.g. Decreased Appetite). Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'UPDATED PER SOURCE ' (Site from DM).	Atoya Adams (b) (4) (b) (4)	08 Apr 2021 19:55:08
User entered 'DECREASED APPETITE' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 17:44:37
User opened query 'Per DM CLR-RQ: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (e.g. Decreased Appetite). Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	Daisy Langarica (b) (4) (b) (4), (b) (6)	08 Apr 2021 17:44:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:15:02
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Added to AE section decreased appetite' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 10:19:59
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Added to AE section decreased appetite' (Site from DM).	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:52:14

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:56:11
User entered 'Appetite Stimulant'	(b) (4), (b) (6)	25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 22:40:51
User closed query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		25 Mar 2021 10:20:02
Query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'He is taking 40 mg per 1 ml.' (Site from DM).	Atoya Adams (b) (4)	24 Mar 2021 18:54:35
User entered '40' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 18:54:22
User opened query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:56:19
User entered '10'	(b) (4), (b) (6)	25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:40:55
User entered 'mg (mg)' reason for change: New Information	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 18:54:22
User entered 'mL (mL)'	(b) (4), (b) (6)	25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:07
User entered empty.		25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:10
User entered 'once daily (QD)'		25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:14
User entered empty.		25 Feb 2021 21:35:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:16
User entered 'Oral (ORAL)'		25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:18
User entered empty.		25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

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

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4)	17 Mar 2021 17:37:20
User entered '10 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:23
User entered '0'		25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:25
User entered 'Yes (Y)'		25 Feb 2021 21:35:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:27
User entered empty.		25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:37:28
User entered 'No (N)'		25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 21:35:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 21:35:25

US3262055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:15:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:55:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:43:55
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	06 Aug 2020 14:40:45

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'USA-US069-2021-MRNA-1273-P301000001'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Atoya'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Adams'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '2121 E. Flamingo Road'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'las vegas'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'NV'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '89119'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:16:37
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
User entered 'US'	(b) (4) System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 14:19:13
User entered '3'	System	11 Mar 2021 18:07:36
User entered '2'	System	02 Mar 2021 15:16:21
User entered '1'	System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'USA-US069-2021-MRNA-1273-P301000001'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Atoya'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Adams'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '2121 E. Flamingo Road'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'las vegas'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'NV'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '89119'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
Reviewed for Safety.		02 Mar 2021 15:16:37
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
User entered 'US'	(b) (4) System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 14:19:13
User entered '3'	System	11 Mar 2021 18:07:36
User entered '2'	System	02 Mar 2021 15:16:21
User entered '1'	System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
User entered '26/Feb/2021 10:57'	(b) (4) System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:15:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
Reviewed for Safety.		02 Mar 2021 15:16:37
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'USA-US069-2021-MRNA-1273-P301000001'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Atoya'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Adams'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '2121 E. Flamingo Road'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'las vegas'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'NV'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '89119'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
Reviewed for Safety.		02 Mar 2021 15:16:37
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
User entered 'US'	(b) (4) System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 14:19:13
User entered '3'	System	11 Mar 2021 18:07:36
User entered '2'	System	02 Mar 2021 15:16:21
User entered '1'	System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:35:28
User entered '02/Mar/2021 10:16'	System	02 Mar 2021 15:16:21

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:15:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4)	17 Mar 2021 17:35:28
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:16:37
User entered 'I'		02 Mar 2021 15:16:21

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'USA-US069-2021-MRNA-1273-P301000001'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Atoya'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Adams'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '2121 E. Flamingo Road'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'las vegas'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'NV'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '89119'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
Reviewed for Safety.		02 Mar 2021 15:16:37
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
User entered 'US'	(b) (4) System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 14:19:13
User entered '3'	System	11 Mar 2021 18:07:36
User entered '2'	System	02 Mar 2021 15:16:21
User entered '1'	System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:35:28
User entered '11/Mar/2021 10:07'	System	11 Mar 2021 18:07:36

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:15:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:19:16
DataPoint Verified.		17 Mar 2021 17:35:28
User entered 'I'		11 Mar 2021 18:07:36

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'USA-US069-2021-MRNA-1273-P301000001'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Yes (Y)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'No (N)'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Atoya'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'Adams'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '2121 E. Flamingo Road'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'las vegas'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered 'NV'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:57:18
User entered '89119'	System	26 Feb 2021 15:56:31

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:35:28
Reviewed for Safety.		02 Mar 2021 15:16:37
User signature succeeded.	Atoya Adams (b) (4)	01 Mar 2021 17:00:27
User entered 'US'	(b) (4) System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 14:19:13
User entered '3'	System	11 Mar 2021 18:07:36
User entered '2'	System	02 Mar 2021 15:16:21
User entered '1'	System	26 Feb 2021 15:57:28

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:15:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:41:49
User entered '25/Mar/2021 10:19'	System	25 Mar 2021 14:19:13

US3262055

Folder: SAE USA-US069-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:15:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:07:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:41:52
Reviewed for Safety.		25 Mar 2021 14:19:16
User entered 'I'		25 Mar 2021 14:19:13