

US3682178 (Prod: UCLA Vine Street Clinic - (CRS))

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:05:19

All time stamps listed in this document are displayed in GMT

US3682178

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

[Participant ID](#)

US3682178

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

US3682178

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:21:28

Generated On: 11 Aug 2021 23:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	01 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" 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) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Condition	PSORIASIS
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Condition	PILONIDAL CYST REMOVAL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Condition	RT HAND TENDON REPAIR
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 23:21:28

Generated On: 11 Aug 2021 23:05:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	16:14 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 16:14
Height (xxx.x)	66 in
Weight (xxx.x)	130 lb
BMI (xxx.x)	21.02642 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) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Date of assessment (dd MMM yyyy) 01 OCT 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 23:21:28

Generated On: 11 Aug 2021 23:05:19

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	01 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:21:28

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:21:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

What was the date of randomization? (dd MMM yyyy) 01 OCT 2020

What was the participant's randomization number? 116139

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

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 19:31:21

Generated On: 11 Aug 2021 23:05:19

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)	01 OCT 2020
Time of assessment (00:00-23:59)	16:14 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 16:14
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 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 19:31:21

Generated On: 11 Aug 2021 23:05:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	17:44 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 17:44
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 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 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

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) 01 OCT 2020

What was the treatment time? (00:00-23:59) 17:02 (24 HR)

Treatment Date and Time (derived) 01 OCT 2020 17:02

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 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 OCT 2020

Collection time (00:00-23:59)

16:54 (24 HR)

Collection date and time (derived)

01 OCT 2020 16:54

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:57	01 OCT 2020 16:57
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

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: 11 Aug 2021 23:05:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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 OCT 2020 17:43

PC Open Date & Time

01 OCT 2020 17:22

PC Close Date & Time

01 OCT 2020 19:52

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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 99.1 °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	01 OCT 2020 20:54
PC Open Date & Time	01 OCT 2020 20:47
PC Close Date & Time	02 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °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	02 OCT 2020 17:22
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 20:41

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 00:00

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

97.8 °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

06 OCT 2020 00:00

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

97.6 °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

07 OCT 2020 08:09

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

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

08 OCT 2020 07:34

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 17:44

PC Open Date & Time

01 OCT 2020 17:22

PC Close Date & Time

01 OCT 2020 19:52

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

01 OCT 2020 20:55

PC Open Date & Time

01 OCT 2020 20:47

PC Close Date & Time

02 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

02 OCT 2020 17:23

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

03 OCT 2020 20:37

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	05 OCT 2020 00:00
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

06 OCT 2020 00:00

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

07 OCT 2020 08:08

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

08 OCT 2020 07:33

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 17:45
PC Open Date & Time	01 OCT 2020 17:22
PC Close Date & Time	01 OCT 2020 19:52

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 20:56
PC Open Date & Time	01 OCT 2020 20:47
PC Close Date & Time	02 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 17:23
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 20:37
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 23:59
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 07:32
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 00:53
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 12:22
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 8

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 09 OCT 2020 00:55

PC Open Date and Time 08 OCT 2020 12:00

PC Close Date and Time 09 OCT 2020 11:59

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 9

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 09 OCT 2020 12:22

PC Open Date and Time 09 OCT 2020 12:00

PC Close Date and Time 10 OCT 2020 11:59

US3682178

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 NOV 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

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

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)	03 NOV 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 15:38
Temperature (xxx.x)	96.6 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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

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)	03 NOV 2020
Time of assessment (00:00-23:59)	16:49 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 16:49
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3682178

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 NOV 2020

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

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	03 NOV 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 03 NOV 2020

What was the treatment time? (00:00-23:59) 16:17 (24 HR)

Treatment Date and Time (derived) 03 NOV 2020 16:17

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

US3682178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 NOV 2020

Collection time (00:00-23:59)

16:08 (24 HR)

Collection date and time (derived)

03 NOV 2020 16:08

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Collection date (dd MMM yyyy)			03 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	03 NOV 2020 16:10
Nasopharyngeal Swab 2	No		

US3682178

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 NOV 2020 16:51

PC Open Date & Time

03 NOV 2020 16:37

PC Close Date & Time

03 NOV 2020 19:07

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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	03 NOV 2020 21:37
PC Open Date & Time	03 NOV 2020 20:02
PC Close Date & Time	04 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

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	100.6 °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	True
PC Time Stamp	04 NOV 2020 21:05
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

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):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 NOV 2020 00:01

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

06 NOV 2020 21:00

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 NOV 2020 00:39

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

96.2 °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

08 NOV 2020 23:50

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

10 NOV 2020 00:32

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 NOV 2020 16:52

PC Open Date & Time

03 NOV 2020 16:37

PC Close Date & Time

03 NOV 2020 19:07

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 NOV 2020 21:37

PC Open Date & Time

03 NOV 2020 20:02

PC Close Date & Time

04 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

04 NOV 2020 21:03

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

06 NOV 2020 00:00

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

06 NOV 2020 21:00

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

07 NOV 2020 23:59

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

08 NOV 2020 23:50

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

10 NOV 2020 00:32

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

No ☒

Yes ☐

PC Time stamp	03 NOV 2020 16:52
PC Open Date & Time	03 NOV 2020 16:37
PC Close Date & Time	03 NOV 2020 19:07

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

No ☒

Yes ☐

PC Time stamp	03 NOV 2020 21:36
PC Open Date & Time	03 NOV 2020 20:02
PC Close Date & Time	04 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 21:04
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	06 NOV 2020 21:00
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	07 NOV 2020 23:59
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

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)

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	08 NOV 2020 23:50
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

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 ☒

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

Yes <input type="checkbox"/>	
PC Time stamp	10 NOV 2020 00:31
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3682178

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:21:11

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 DEC 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

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	15:30 (24 HR)
Vital Signs Date and Time (derived)	01 DEC 2020 15:30
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682178

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 DEC 2020

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

US3682178

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 DEC 2020
Collection time (00:00-23:59)	15:44 (24 HR)
Collection date and time (derived)	01 DEC 2020 15:44

US3682178

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:31:21

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 61

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

01 DEC 2020 12:25:36

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 68
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	07 DEC 2020 15:45:58
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 12:01:28
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 00:01:24
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 00:01:43
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 00:24:44
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 01:19:23

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 07:18:11
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 02:59:36

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 13:10:41
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

06 FEB 2021 00:01:34

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 07:39:58

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 21:34:24

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 15:01:54

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 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	08 MAR 2021 12:01:35
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 18:59:48

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 10:42:12

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 12:00:51
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 APR 2021 12:14:17
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

12 APR 2021 12:07:13

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 12:18:15
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 22:25:22

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 14:54:02

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 250

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

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

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 <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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 <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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 <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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 <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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 425

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

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

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

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

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 432

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

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

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

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

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

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

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 <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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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23 MAR 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 <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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 649

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

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

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

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

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

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

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2022 00:01
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Patient Cloud Close Date & Time	16 NOV 2022 23:59
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US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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="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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

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

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3682178

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:17:44

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:17:43

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3682178

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:10:35

Generated On: 11 Aug 2021 23:05:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:10:35

Generated On: 11 Aug 2021 23:05:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 APR 2021
Time of assessment (00:00-23:59)	15:49 (24 HR)
Vital Signs Date and Time (derived)	27 APR 2021 15:49
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:10:35

Generated On: 11 Aug 2021 23:05:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 APR 2021

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

US3682178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:10:35

Generated On: 11 Aug 2021 23:05:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 APR 2021

Collection time (00:00-23:59)

15:59 (24 HR)

Collection date and time (derived)

27 APR 2021 15:59

US3682178

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:10:35

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682178

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3682178

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:05:19

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"/>

US3682178

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 23:05:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3682178

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

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

Visit date (dd MMM yyyy)	15 JAN 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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US3682178

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Date of updated informed consent (*dd MMM yyyy*) 15 JAN 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*) 15 JAN 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 _____

US3682178

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	15 JAN 2021
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Collection time (00:00-23:59)	15:40 (24 HR)
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Collection date and time (derived)	15 JAN 2021 15:40
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US3682178

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	15:36
Collection Date and Time (derived)	15 JAN 2021 15:36

US3682178

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 21:19:27

Generated On: 11 Aug 2021 23:05:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 21:19:27

Generated On: 11 Aug 2021 23:05:19

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 21:19:27

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 21:19:27

Generated On: 11 Aug 2021 23:05:19

AEID

Adverse event

RIGHT UNDERARM
LYMPHADENOPATHY,
IPSILATERAL TO INJECTION
SITE

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☒
No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 06 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 10 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 21:19:27

Generated On: 11 Aug 2021 23:05:19

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

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EAB) (1725)

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US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

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

Yes ☒

No ☐

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

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Name of Medication TRILEGEST

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	1 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN, MUSCLE
ACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FEVER,FATIGUE, INJ SITE PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Name of Medication EXCEDRIN - ASPIRIN,
ACETAMINOPHEN, CAFFEINE

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 250/250/65

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 5 NOV 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Name of Medication EXCEDRIN - ASPIRIN,
ACETAMINOPHEN, CAFFEINE

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 250/250/65

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Name of Medication PRENATAL MUTLIVITAMIN
WITH 50MG OF
DOCOSAHEXAENOIC ACID

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 JAN 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"/>

US3682178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 21:01:12

Generated On: 11 Aug 2021 23:05:19

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3682178

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:05:19

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

US3682178

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:05:19

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 ☐

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

SAEID	USA-US081-2021-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

SAEID	USA-US081-2021-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/MAR/2021 15:04
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

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 21:01:13

Generated On: 11 Aug 2021 23:05:19

SAEID	USA-US081-2021-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	11/MAR/2021 10:33
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

US3682178 (Prod: UCLA Vine Street Clinic - (CRS))

US3682178

Form: Participant Creation

Generated On: 11 Aug 2021 23:05:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'US3682178'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 23:22:35

US3682178

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:25:41

US3682178

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 23:22:36

US3682178

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[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 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:25:41

US3682178

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'SCRN'	System	01 Oct 2020 23:25:41

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered (b) (6) 1986'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 23:22:37

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '33'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'YEARS'	System	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '33'	System	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Female (F)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'I'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:12:59

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'Oct 2020'	System	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '2020'	System	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:01

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 23:22:36

US3682178

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'I'	System	01 Oct 2020 23:26:07

US3682178

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:07

US3682178

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 23:05:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:15

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 23:27:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 23:27:50
Data point term sent to Coder	System	01 Oct 2020 23:27:03
User entered 'PSORIASIS'	(b) (4), (b) (6)	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'UN UNK 2002'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'Jan 2002'	System	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '2002'	System	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered empty.	System	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered empty.	System	01 Oct 2020 23:26:33

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Pilonidal sinus repair, LLT: Pilonidal cyst excision - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 23:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 23:28:50
Data point term sent to Coder	System	01 Oct 2020 23:28:04
User entered 'PILONIDAL CYST REMOVAL'	(b) (4), (b) (6)	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'Jan 2005'	System	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '2005'	System	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'Jan 2005'	System	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '2005'	System	01 Oct 2020 23:27:52

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tenoplasty, LLT: Tendon repair - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 23:29:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 23:29:51
Data point term sent to Coder	System	01 Oct 2020 23:29:04
User entered 'RT HAND TENDON REPAIR'	(b) (4), (b) (6)	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 23:28:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 23:28:24
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 23:28:17
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'Jan 2008'	System	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '2008'	System	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'Jan 2008'	System	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '2008'	System	01 Oct 2020 23:28:17

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '01 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '16:14'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '01 Oct 2020 16:14'	System	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '66' in	(b) (4)	
	Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48
DataPoint set to visible.	(b) (4)	
	System	01 Oct 2020 23:26:07

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '130' lb	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48
DataPoint set to visible.	(b) (4) System	01 Oct 2020 23:26:07

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '21.02642'	System	02 Oct 2020 00:11:48
DataPoint set to visible.	System	01 Oct 2020 23:26:07

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'kg/m2'	System	02 Oct 2020 00:11:48
DataPoint set to visible.	System	01 Oct 2020 23:26:07

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'bpm'	System	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'breaths/min'	System	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'mmHg'	System	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'mmHg'	System	02 Oct 2020 00:11:48

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09

US3682178

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09

US3682178

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:35

US3682178

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:35

US3682178

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '01 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:22

US3682178

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:22

US3682178

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:22

US3682178

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:19

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:22

US3682178

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:22

US3682178

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:19

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:22

US3682178

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:22

US3682178

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:19

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:22

US3682178

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:35

US3682178

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '01 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:35

US3682178

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'Urine (URINE)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:35

US3682178

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'Negative (NEGATIVE)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:35

US3682178

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:35

US3682178

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:35

US3682178

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:35

US3682178

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered empty.	System	02 Oct 2020 00:13:35

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:28
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:28:54

US3682178

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:29:17

US3682178

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:29:17

US3682178

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:29:17

US3682178

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'VISIT1'	System	01 Oct 2020 23:29:17

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 23:42:42

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '116139'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 23:42:42

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 23:42:42

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:52

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:52

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:52

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:52

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:52

US3682178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:19

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:13:52
DataPoint set to visible.	(b) (4) System	01 Oct 2020 23:26:01

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 08:51:42
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'data corrected' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 23:22:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Oct 2020 23:22:12
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 19:54:25
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 23:22:12
User entered empty.	Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32
	(b) (4)	

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 08:51:42
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'data corrected' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 23:22:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Oct 2020 23:22:12
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 19:54:25
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 23:22:12
User entered empty.	Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32
	(b) (4)	

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User accepted default value 'Pre-Dose (PREDOSE)'	Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16:14'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '01 Oct 2020 16:14'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '98.0' F	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '81'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'bpm'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'breaths/min'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '110'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '75'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 08:51:42
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'data corrected' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 23:22:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Oct 2020 23:22:12
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 19:54:25
User entered empty.	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 23:22:12
User entered empty.	Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32
	(b) (4)	

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User accepted default value 'Post-Dose (POSTDOSE)'	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '17:44'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '01 Oct 2020 17:44'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '96.8' F	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '72'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'bpm'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'breaths/min'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '106'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '74'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	02 Oct 2020 00:55:32

US3682178

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:02

US3682178

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:02

US3682178

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User closed query 'Per CDM: Please note if screening and VID1 date is on the same day, kindly complete the Pregnancy Test form on the screening folder and change the Pregnancy Test performed on VID1 to "NO". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 07:17:36
Query 'Per CDM: Please note if screening and VID1 date is on the same day, kindly complete the Pregnancy Test form on the screening folder and change the Pregnancy Test performed on VID1 to "NO". Thank you.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:21:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:21:12
User opened query 'Per CDM: Please note if screening and VID1 date is on the same day, kindly complete the Pregnancy Test form on the screening folder and change the Pregnancy Test performed on VID1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:03:43
User entered 'Yes (Y)'	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:14:54

US3682178

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:21:12
User entered '01 Oct 2020'	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:14:54

US3682178

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:21:12
User entered 'Urine (URINE)'	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:14:54

US3682178

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:21:12
User entered 'Negative (NEGATIVE)'	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:14:54

US3682178

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User closed query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:31:04
Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 18:26:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 18:26:05
User opened query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:22:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:21:12
User entered 'No (N)'	Schuyler Thomas (b) (4) (b) (4)	02 Oct 2020 00:14:54

US3682178

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:54

US3682178

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	Schuyler Thomas (b) (4)	02 Oct 2020 00:14:54

US3682178

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered empty.	System	02 Oct 2020 00:14:54

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '17:02'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '01 Oct 2020 17:02'	System	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'ONCE'	System	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 00:14:33

US3682178

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 01:04:08

US3682178

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 01:04:08

US3682178

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16:54'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 01:04:08

US3682178

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '01 Oct 2020 16:54'	System	02 Oct 2020 01:04:08

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:05:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:05:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16:57'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '01 Oct 2020 16:57'	System	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered empty.	System	02 Oct 2020 01:04:22

US3682178

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	02 Oct 2020 00:14:40

US3682178

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '1'	System	02 Oct 2020 00:14:40

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:43:05', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a4d68f1d-f48f-448d-a5f1-6c460689576f' User entered 'Yes (Y)'	System	02 Oct 2020 00:43:38
	System	02 Oct 2020 00:43:38

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:43:12', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a4d68f1d-f48f-448d-a5f1-6c460689576f' User entered '96.8'	System	02 Oct 2020 00:43:38
	System	02 Oct 2020 00:43:38

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:43:18', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a4d68f1d-f48f-448d-a5f1-6c460689576f' User entered 'No (N)'	System	02 Oct 2020 00:43:38
	System	02 Oct 2020 00:43:38

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:43:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a4d68f1d-f48f-448d-a5f1-6c460689576f' User entered '01 Oct 2020 17:43'	System	02 Oct 2020 00:43:38
	System	02 Oct 2020 00:43:38

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 17:22'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 19:52'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:54:01', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b471cb3c-ca9c-468f-aafd-67a453a51b28'	System	02 Oct 2020 03:54:22
User entered 'Yes (Y)'	System	02 Oct 2020 03:54:22

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:54:08', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b471cb3c-ca9c-468f-aafd-67a453a51b28' User entered '99.1'	System	02 Oct 2020 03:54:22
	System	02 Oct 2020 03:54:22

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:54:12', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b471cb3c-ca9c-468f-aafd-67a453a51b28'	System	02 Oct 2020 03:54:22
User entered 'No (N)'	System	02 Oct 2020 03:54:22

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:54:20', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b471cb3c-ca9c-468f-aafd-67a453a51b28'	System	02 Oct 2020 03:54:22
User entered '01 Oct 2020 20:54'	System	02 Oct 2020 03:54:22

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 20:47'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '02 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 2'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:17:15', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b2c7e68a-12c7-4ae0-900b-39510a3b3d61' User entered 'Yes (Y)'	System	03 Oct 2020 00:22:56
	System	03 Oct 2020 00:22:56

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:17:23', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b2c7e68a-12c7-4ae0-900b-39510a3b3d61' User entered '97.9'	System	03 Oct 2020 00:22:56
	System	03 Oct 2020 00:22:56

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:17:28', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b2c7e68a-12c7-4ae0-900b-39510a3b3d61'	System	03 Oct 2020 00:22:56
User entered 'Yes (Y)'	System	03 Oct 2020 00:22:56

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
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 'Taken Ibuprofen' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 07:15:10
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 'Taken Ibuprofen' (Site from System).	Susan Reed (b) (4)	06 Oct 2020 00:35:02
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).	System	03 Oct 2020 00:22:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:17:34', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b2c7e68a-12c7-4ae0-900b-39510a3b3d61'	System	03 Oct 2020 00:22:56
User entered '1'	System	03 Oct 2020 00:22:56

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:17:34', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b2c7e68a-12c7-4ae0-900b-39510a3b3d61' User entered '0'	System	03 Oct 2020 00:22:56
	System	03 Oct 2020 00:22:56

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:22:07', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b2c7e68a-12c7-4ae0-900b-39510a3b3d61' User entered '02 Oct 2020 17:22'	System	03 Oct 2020 00:22:56
	System	03 Oct 2020 00:22:56

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 3'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:40:57', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'f6ec2cd2-070e-490f-82d5-b2d906e9c1c7' User entered 'Yes (Y)'	System	04 Oct 2020 03:41:13
	System	04 Oct 2020 03:41:13

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:41:03', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'f6ec2cd2-070e-490f-82d5-b2d906e9c1c7' User entered '97.7'	System	04 Oct 2020 03:41:13
	System	04 Oct 2020 03:41:13

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:41:05', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'f6ec2cd2-070e-490f-82d5-b2d906e9c1c7'	System	04 Oct 2020 03:41:13
User entered 'No (N)'	System	04 Oct 2020 03:41:13

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:41:10', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'f6ec2cd2-070e-490f-82d5-b2d906e9c1c7' User entered '03 Oct 2020 20:41'	System	04 Oct 2020 03:41:13
	System	04 Oct 2020 03:41:13

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 4'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T00:00:14', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c3de3954-9a4d-4b70-b3de-c7890e95687f' User entered 'Yes (Y)'	System	05 Oct 2020 07:00:35
	System	05 Oct 2020 07:00:35

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T00:00:25', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c3de3954-9a4d-4b70-b3de-c7890e95687f' User entered '96.7'	System	05 Oct 2020 07:00:35
	System	05 Oct 2020 07:00:35

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T00:00:28', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c3de3954-9a4d-4b70-b3de-c7890e95687f' User entered 'No (N)'	System	05 Oct 2020 07:00:35
	System	05 Oct 2020 07:00:35

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T00:00:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c3de3954-9a4d-4b70-b3de-c7890e95687f' User entered '05 Oct 2020 00:00'	System	05 Oct 2020 07:00:35
	System	05 Oct 2020 07:00:35

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 5'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-06T00:00:06', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '125249e9-37d4-44a5-b52d-b01c96af985b' User entered 'Yes (Y)'	System	06 Oct 2020 07:00:24
	System	06 Oct 2020 07:00:24

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-06T00:00:17', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '125249e9-37d4-44a5-b52d-b01c96af985b' User entered '97.8'	System	06 Oct 2020 07:00:24
	System	06 Oct 2020 07:00:24

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-06T00:00:18', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '125249e9-37d4-44a5-b52d-b01c96af985b' User entered 'No (N)'	System	06 Oct 2020 07:00:24
	System	06 Oct 2020 07:00:24

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-06T00:00:23', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '125249e9-37d4-44a5-b52d-b01c96af985b' User entered '06 Oct 2020 00:00'	System	06 Oct 2020 07:00:24
	System	06 Oct 2020 07:00:24

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 6'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:55', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b11af9e6-7d3a-4f16-9a1e-6200f3d9280c' User entered 'Yes (Y)'	System	07 Oct 2020 15:09:08
	System	07 Oct 2020 15:09:08

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:09:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b11af9e6-7d3a-4f16-9a1e-6200f3d9280c' User entered '97.6'	System	07 Oct 2020 15:09:08
	System	07 Oct 2020 15:09:08

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:09:03', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b11af9e6-7d3a-4f16-9a1e-6200f3d9280c'	System	07 Oct 2020 15:09:08
User entered 'No (N)'	System	07 Oct 2020 15:09:08

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:09:06', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b11af9e6-7d3a-4f16-9a1e-6200f3d9280c' User entered '07 Oct 2020 08:09'	System	07 Oct 2020 15:09:08
	System	07 Oct 2020 15:09:08

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 7'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:33:41', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91b529ad-c9f7-44be-a89d-68e22a5eef66' User entered 'Yes (Y)'	System	08 Oct 2020 14:34:10
	System	08 Oct 2020 14:34:10

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:33:51', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91b529ad-c9f7-44be-a89d-68e22a5eef66' User entered '97.5'	System	08 Oct 2020 14:34:10
	System	08 Oct 2020 14:34:10

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:34:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91b529ad-c9f7-44be-a89d-68e22a5eef66'	System	08 Oct 2020 14:34:10
User entered 'No (N)'	System	08 Oct 2020 14:34:10

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:34:07', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91b529ad-c9f7-44be-a89d-68e22a5eef66' User entered '08 Oct 2020 07:34'	System	08 Oct 2020 14:34:10
	System	08 Oct 2020 14:34:10

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:43:56', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd8536c40-38f0-49c5-8924-572306d9e738'	System	02 Oct 2020 00:44:38
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 00:44:38

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:04', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd8536c40-38f0-49c5-8924-572306d9e738' User entered 'No (N)'	System	02 Oct 2020 00:44:38
	System	02 Oct 2020 00:44:38

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:16', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd8536c40-38f0-49c5-8924-572306d9e738'	System	02 Oct 2020 00:44:38
User entered 'No (N)'	System	02 Oct 2020 00:44:38

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:23', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd8536c40-38f0-49c5-8924-572306d9e738' User entered 'None (1)'	System	02 Oct 2020 00:44:38
	System	02 Oct 2020 00:44:38

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:35', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd8536c40-38f0-49c5-8924-572306d9e738' User entered '01 Oct 2020 17:44'	System	02 Oct 2020 00:44:38
	System	02 Oct 2020 00:44:38

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 17:22'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 19:52'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:54:34', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c36790d8-f6b9-469d-9c36-4f2bf8a04b1b'	System	02 Oct 2020 03:56:02
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 03:56:02

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:55:02', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c36790d8-f6b9-469d-9c36-4f2bf8a04b1b' User entered 'No (N)'	System	02 Oct 2020 03:56:02
	System	02 Oct 2020 03:56:02

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:55:35', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c36790d8-f6b9-469d-9c36-4f2bf8a04b1b' User entered 'No (N)'	System	02 Oct 2020 03:56:02
	System	02 Oct 2020 03:56:02

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:55:49', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c36790d8-f6b9-469d-9c36-4f2bf8a04b1b' User entered 'None (1)'	System	02 Oct 2020 03:56:02
	System	02 Oct 2020 03:56:02

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:55:57', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c36790d8-f6b9-469d-9c36-4f2bf8a04b1b' User entered '01 Oct 2020 20:55'	System	02 Oct 2020 03:56:02
	System	02 Oct 2020 03:56:02

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 20:47'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '02 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 2'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:22:40', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '13264071-4cdf-491e-a213-de1e4a2ad904'	System	03 Oct 2020 00:23:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Oct 2020 00:23:18

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:22:48', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '13264071-4cdf-491e-a213-de1e4a2ad904'	System	03 Oct 2020 00:23:18
User entered 'No (N)'	System	03 Oct 2020 00:23:18

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:22:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '13264071-4cdf-491e-a213-de1e4a2ad904' User entered 'No (N)'	System	03 Oct 2020 00:23:18
	System	03 Oct 2020 00:23:18

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:22:59', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '13264071-4cdf-491e-a213-de1e4a2ad904'	System	03 Oct 2020 00:23:18
User entered 'None (1)'	System	03 Oct 2020 00:23:18

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:03', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '13264071-4cdf-491e-a213-de1e4a2ad904'	System	03 Oct 2020 00:23:18
User entered '02 Oct 2020 17:23'	System	03 Oct 2020 00:23:18

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 3'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:36:45', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a7f38e16-5d47-493b-aedc-3bd9f95e000a'	System	04 Oct 2020 03:37:07
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 03:37:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:36:47', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a7f38e16-5d47-493b-aedc-3bd9f95e000a' User entered 'No (N)'	System	04 Oct 2020 03:37:07
	System	04 Oct 2020 03:37:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:36:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a7f38e16-5d47-493b-aedc-3bd9f95e000a' User entered 'No (N)'	System	04 Oct 2020 03:37:07
	System	04 Oct 2020 03:37:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:01', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a7f38e16-5d47-493b-aedc-3bd9f95e000a' User entered 'None (1)'	System	04 Oct 2020 03:37:07
	System	04 Oct 2020 03:37:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:05', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a7f38e16-5d47-493b-aedc-3bd9f95e000a' User entered '03 Oct 2020 20:37'	System	04 Oct 2020 03:37:07
	System	04 Oct 2020 03:37:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 4'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:56', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd252bb2b-a7a4-4912-9a21-bfa3d48defde'	System	05 Oct 2020 07:00:11
User entered 'None (1)'	System	05 Oct 2020 07:00:11

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:59', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd252bb2b-a7a4-4912-9a21-bfa3d48defde' User entered 'No (N)'	System	05 Oct 2020 07:00:11
	System	05 Oct 2020 07:00:11

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T00:00:01', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd252bb2b-a7a4-4912-9a21-bfa3d48defde' User entered 'No (N)'	System	05 Oct 2020 07:00:11
	System	05 Oct 2020 07:00:11

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T00:00:04', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd252bb2b-a7a4-4912-9a21-bfa3d48defde' User entered 'None (1)'	System	05 Oct 2020 07:00:11
	System	05 Oct 2020 07:00:11

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T00:00:08', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd252bb2b-a7a4-4912-9a21-bfa3d48defde' User entered '05 Oct 2020 00:00'	System	05 Oct 2020 07:00:11
	System	05 Oct 2020 07:00:11

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 5'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cf54300a-f36e-487a-87e1-b87c24adcc44'	System	06 Oct 2020 07:00:07
User entered 'None (1)'	System	06 Oct 2020 07:00:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:52', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cf54300a-f36e-487a-87e1-b87c24adcc44'	System	06 Oct 2020 07:00:07
User entered 'No (N)'	System	06 Oct 2020 07:00:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cf54300a-f36e-487a-87e1-b87c24adcc44'	System	06 Oct 2020 07:00:07
User entered 'No (N)'	System	06 Oct 2020 07:00:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:57', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cf54300a-f36e-487a-87e1-b87c24adcc44'	System	06 Oct 2020 07:00:07
User entered 'None (1)'	System	06 Oct 2020 07:00:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-06T00:00:01', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cf54300a-f36e-487a-87e1-b87c24adcc44'	System	06 Oct 2020 07:00:07
User entered '06 Oct 2020 00:00'	System	06 Oct 2020 07:00:07

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 6'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:28', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e3268702-64cb-417f-9538-fea0aca8366d' User entered 'None (1)'	System	07 Oct 2020 15:08:51
	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:30', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e3268702-64cb-417f-9538-fea0aca8366d' User entered 'No (N)'	System	07 Oct 2020 15:08:51
	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:42', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e3268702-64cb-417f-9538-fea0aca8366d' User entered 'No (N)'	System	07 Oct 2020 15:08:51
	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:45', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e3268702-64cb-417f-9538-fea0aca8366d'	System	07 Oct 2020 15:08:51
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e3268702-64cb-417f-9538-fea0aca8366d' User entered '07 Oct 2020 08:08'	System	07 Oct 2020 15:08:51
	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 7'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:40', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b254e7c8-12b8-412c-b5cd-ae9060a15986'	System	08 Oct 2020 14:33:03
User entered 'None (1)'	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:48', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b254e7c8-12b8-412c-b5cd-ae9060a15986' User entered 'No (N)'	System	08 Oct 2020 14:33:03
	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b254e7c8-12b8-412c-b5cd-ae9060a15986' User entered 'No (N)'	System	08 Oct 2020 14:33:03
	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:55', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b254e7c8-12b8-412c-b5cd-ae9060a15986'	System	08 Oct 2020 14:33:03
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:33:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b254e7c8-12b8-412c-b5cd-ae9060a15986' User entered '08 Oct 2020 07:33'	System	08 Oct 2020 14:33:03
	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:42', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b0881236-9375-4b27-ad03-b5ed2b7b20f6' User entered 'None (0)'	System	02 Oct 2020 00:45:18
	System	02 Oct 2020 00:45:18

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:46', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b0881236-9375-4b27-ad03-b5ed2b7b20f6' User entered 'None (0)'	System	02 Oct 2020 00:45:18
	System	02 Oct 2020 00:45:18

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b0881236-9375-4b27-ad03-b5ed2b7b20f6'	System	02 Oct 2020 00:45:18
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:45:18

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:57', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b0881236-9375-4b27-ad03-b5ed2b7b20f6' User entered 'None (0)'	System	02 Oct 2020 00:45:18
	System	02 Oct 2020 00:45:18

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:44:59', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b0881236-9375-4b27-ad03-b5ed2b7b20f6' User entered 'None (0)'	System	02 Oct 2020 00:45:18
	System	02 Oct 2020 00:45:18

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:45:02', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b0881236-9375-4b27-ad03-b5ed2b7b20f6' User entered 'None (0)'	System	02 Oct 2020 00:45:18
	System	02 Oct 2020 00:45:18

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:45:09', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b0881236-9375-4b27-ad03-b5ed2b7b20f6' User entered 'No (N)'	System	02 Oct 2020 00:45:18
	System	02 Oct 2020 00:45:18

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T17:45:15', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b0881236-9375-4b27-ad03-b5ed2b7b20f6'	System	02 Oct 2020 00:45:18
User entered '01 Oct 2020 17:45'	System	02 Oct 2020 00:45:18

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 17:22'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 19:52'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:56:04', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '46ec4968-da84-4898-85dc-487cd9148d3a' User entered 'None (0)'	System	02 Oct 2020 03:56:53
	System	02 Oct 2020 03:56:53

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:56:11', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '46ec4968-da84-4898-85dc-487cd9148d3a'	System	02 Oct 2020 03:56:53
User entered 'No interference with activity (1)'	System	02 Oct 2020 03:56:53

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:56:18', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '46ec4968-da84-4898-85dc-487cd9148d3a'	System	02 Oct 2020 03:56:53
User entered 'No interference with activity (1)'	System	02 Oct 2020 03:56:53

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:56:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '46ec4968-da84-4898-85dc-487cd9148d3a' User entered 'None (0)'	System	02 Oct 2020 03:56:53
	System	02 Oct 2020 03:56:53

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:56:34', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '46ec4968-da84-4898-85dc-487cd9148d3a' User entered 'None (0)'	System	02 Oct 2020 03:56:53
	System	02 Oct 2020 03:56:53

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:56:38', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '46ec4968-da84-4898-85dc-487cd9148d3a' User entered 'None (0)'	System	02 Oct 2020 03:56:53
	System	02 Oct 2020 03:56:53

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:56:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '46ec4968-da84-4898-85dc-487cd9148d3a' User entered 'No (N)'	System	02 Oct 2020 03:56:53
	System	02 Oct 2020 03:56:53

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-01T20:56:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '46ec4968-da84-4898-85dc-487cd9148d3a'	System	02 Oct 2020 03:56:53
User entered '01 Oct 2020 20:56'	System	02 Oct 2020 03:56:53

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '01 Oct 2020 20:47'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '02 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 2'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:10', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2955c09d-c57d-4aff-905f-78c853541602'	System	03 Oct 2020 00:23:42
User entered 'None (0)'	System	03 Oct 2020 00:23:42

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:13', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2955c09d-c57d-4aff-905f-78c853541602' User entered 'None (0)'	System	03 Oct 2020 00:23:42
	System	03 Oct 2020 00:23:42

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:17', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2955c09d-c57d-4aff-905f-78c853541602'	System	03 Oct 2020 00:23:42
User entered 'No interference with activity (1)'	System	03 Oct 2020 00:23:42

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:25', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2955c09d-c57d-4aff-905f-78c853541602' User entered 'None (0)'	System	03 Oct 2020 00:23:42
	System	03 Oct 2020 00:23:42

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:27', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2955c09d-c57d-4aff-905f-78c853541602' User entered 'None (0)'	System	03 Oct 2020 00:23:42
	System	03 Oct 2020 00:23:42

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2955c09d-c57d-4aff-905f-78c853541602'	System	03 Oct 2020 00:23:42
User entered 'No interference with activity (1)'	System	03 Oct 2020 00:23:42

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:37', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2955c09d-c57d-4aff-905f-78c853541602'	System	03 Oct 2020 00:23:42
User entered 'No (N)'	System	03 Oct 2020 00:23:42

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-02T17:23:40', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2955c09d-c57d-4aff-905f-78c853541602'	System	03 Oct 2020 00:23:42
User entered '02 Oct 2020 17:23'	System	03 Oct 2020 00:23:42

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 3'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:08', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '5fe79905-7796-41b0-9df5-a723e67edae4' User entered 'None (0)'	System	04 Oct 2020 03:37:31
	System	04 Oct 2020 03:37:31

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:10', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '5fe79905-7796-41b0-9df5-a723e67edae4' User entered 'None (0)'	System	04 Oct 2020 03:37:31
	System	04 Oct 2020 03:37:31

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:12', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '5fe79905-7796-41b0-9df5-a723e67edae4' User entered 'None (0)'	System	04 Oct 2020 03:37:31
	System	04 Oct 2020 03:37:31

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:14', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '5fe79905-7796-41b0-9df5-a723e67edae4' User entered 'None (0)'	System	04 Oct 2020 03:37:31
	System	04 Oct 2020 03:37:31

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:16', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '5fe79905-7796-41b0-9df5-a723e67edae4' User entered 'None (0)'	System	04 Oct 2020 03:37:31
	System	04 Oct 2020 03:37:31

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:18', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '5fe79905-7796-41b0-9df5-a723e67edae4' User entered 'None (0)'	System	04 Oct 2020 03:37:31
	System	04 Oct 2020 03:37:31

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:24', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '5fe79905-7796-41b0-9df5-a723e67edae4' User entered 'No (N)'	System	04 Oct 2020 03:37:31
	System	04 Oct 2020 03:37:31

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-03T20:37:29', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '5fe79905-7796-41b0-9df5-a723e67edae4' User entered '03 Oct 2020 20:37'	System	04 Oct 2020 03:37:31
	System	04 Oct 2020 03:37:31

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 4'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:38', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2cc77d01-bb09-4b84-86ee-cdb633baf7da' User entered 'None (0)'	System	05 Oct 2020 06:59:54
	System	05 Oct 2020 06:59:54

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:40', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2cc77d01-bb09-4b84-86ee-cdb633baf7da' User entered 'None (0)'	System	05 Oct 2020 06:59:54
	System	05 Oct 2020 06:59:54

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:42', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2cc77d01-bb09-4b84-86ee-cdb633baf7da' User entered 'None (0)'	System	05 Oct 2020 06:59:54
	System	05 Oct 2020 06:59:54

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:44', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2cc77d01-bb09-4b84-86ee-cdb633baf7da' User entered 'None (0)'	System	05 Oct 2020 06:59:54
	System	05 Oct 2020 06:59:54

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:46', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2cc77d01-bb09-4b84-86ee-cdb633baf7da' User entered 'None (0)'	System	05 Oct 2020 06:59:54
	System	05 Oct 2020 06:59:54

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:47', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2cc77d01-bb09-4b84-86ee-cdb633baf7da' User entered 'None (0)'	System	05 Oct 2020 06:59:54
	System	05 Oct 2020 06:59:54

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:49', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2cc77d01-bb09-4b84-86ee-cdb633baf7da' User entered 'No (N)'	System	05 Oct 2020 06:59:54
	System	05 Oct 2020 06:59:54

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-04T23:59:52', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '2cc77d01-bb09-4b84-86ee-cdb633baf7da' User entered '04 Oct 2020 23:59'	System	05 Oct 2020 06:59:54
	System	05 Oct 2020 06:59:54

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 5'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:27', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '76604ef5-b329-447a-b5eb-5c14bc06bfc8' User entered 'None (0)'	System	06 Oct 2020 06:59:48
	System	06 Oct 2020 06:59:48

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '76604ef5-b329-447a-b5eb-5c14bc06bfc8' User entered 'None (0)'	System	06 Oct 2020 06:59:48
	System	06 Oct 2020 06:59:48

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:32', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '76604ef5-b329-447a-b5eb-5c14bc06bfc8' User entered 'None (0)'	System	06 Oct 2020 06:59:48
	System	06 Oct 2020 06:59:48

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:36', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '76604ef5-b329-447a-b5eb-5c14bc06bfc8' User entered 'None (0)'	System	06 Oct 2020 06:59:48
	System	06 Oct 2020 06:59:48

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:38', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '76604ef5-b329-447a-b5eb-5c14bc06bfc8' User entered 'None (0)'	System	06 Oct 2020 06:59:48
	System	06 Oct 2020 06:59:48

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:39', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '76604ef5-b329-447a-b5eb-5c14bc06bfc8' User entered 'None (0)'	System	06 Oct 2020 06:59:48
	System	06 Oct 2020 06:59:48

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '76604ef5-b329-447a-b5eb-5c14bc06bfc8' User entered 'No (N)'	System	06 Oct 2020 06:59:48
	System	06 Oct 2020 06:59:48

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-05T23:59:45', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '76604ef5-b329-447a-b5eb-5c14bc06bfc8' User entered '05 Oct 2020 23:59'	System	06 Oct 2020 06:59:48
	System	06 Oct 2020 06:59:48

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 6'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:07:53', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'caae5bb0-d011-4a7b-be87-bcb9863c598c' User entered 'None (0)'	System	07 Oct 2020 15:08:19
	System	07 Oct 2020 15:08:19

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:07:55', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'caae5bb0-d011-4a7b-be87-bcb9863c598c' User entered 'None (0)'	System	07 Oct 2020 15:08:19
	System	07 Oct 2020 15:08:19

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:07:57', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'caae5bb0-d011-4a7b-be87-bcb9863c598c' User entered 'None (0)'	System	07 Oct 2020 15:08:19
	System	07 Oct 2020 15:08:19

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:07:59', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'caae5bb0-d011-4a7b-be87-bcb9863c598c' User entered 'None (0)'	System	07 Oct 2020 15:08:19
	System	07 Oct 2020 15:08:19

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'caae5bb0-d011-4a7b-be87-bcb9863c598c' User entered 'None (0)'	System	07 Oct 2020 15:08:19
	System	07 Oct 2020 15:08:19

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:02', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'caae5bb0-d011-4a7b-be87-bcb9863c598c' User entered 'None (0)'	System	07 Oct 2020 15:08:19
	System	07 Oct 2020 15:08:19

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:11', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'caae5bb0-d011-4a7b-be87-bcb9863c598c' User entered 'No (N)'	System	07 Oct 2020 15:08:19
	System	07 Oct 2020 15:08:19

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-07T08:08:17', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'caae5bb0-d011-4a7b-be87-bcb9863c598c' User entered '07 Oct 2020 08:08'	System	07 Oct 2020 15:08:19
	System	07 Oct 2020 15:08:19

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	02 Oct 2020 00:14:33
User entered 'Day 7'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:13', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '90bbd6f7-5a9e-4f36-b301-bbf69712570a' User entered 'None (0)'	System	08 Oct 2020 14:32:41
	System	08 Oct 2020 14:32:41

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:17', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '90bbd6f7-5a9e-4f36-b301-bbf69712570a' User entered 'None (0)'	System	08 Oct 2020 14:32:41
	System	08 Oct 2020 14:32:41

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:19', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '90bbd6f7-5a9e-4f36-b301-bbf69712570a' User entered 'None (0)'	System	08 Oct 2020 14:32:41
	System	08 Oct 2020 14:32:41

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:21', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '90bbd6f7-5a9e-4f36-b301-bbf69712570a' User entered 'None (0)'	System	08 Oct 2020 14:32:41
	System	08 Oct 2020 14:32:41

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:23', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '90bbd6f7-5a9e-4f36-b301-bbf69712570a' User entered 'None (0)'	System	08 Oct 2020 14:32:41
	System	08 Oct 2020 14:32:41

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:26', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '90bbd6f7-5a9e-4f36-b301-bbf69712570a' User entered 'None (0)'	System	08 Oct 2020 14:32:41
	System	08 Oct 2020 14:32:41

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:28', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '90bbd6f7-5a9e-4f36-b301-bbf69712570a' User entered 'No (N)'	System	08 Oct 2020 14:32:41
	System	08 Oct 2020 14:32:41

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-08T07:32:35', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '90bbd6f7-5a9e-4f36-b301-bbf69712570a' User entered '08 Oct 2020 07:32'	System	08 Oct 2020 14:32:41
	System	08 Oct 2020 14:32:41

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 00:14:33

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	07 Oct 2020 15:08:51
User entered 'Day 8'	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-09T00:53:47', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '8c0d0d66-ba8b-4607-806e-61cd233be6b5' User entered 'No (N)'	System	09 Oct 2020 07:53:54
	System	09 Oct 2020 07:53:54

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-09T00:53:51', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '8c0d0d66-ba8b-4607-806e-61cd233be6b5' User entered '09 Oct 2020 00:53'	System	09 Oct 2020 07:53:54
	System	09 Oct 2020 07:53:54

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	08 Oct 2020 14:33:03
User entered 'Day 9'	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-09T12:22:19', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '1ad4a140-660e-4296-90f7-8e3edc171034'	System	09 Oct 2020 19:22:29
User entered 'No (N)'	System	09 Oct 2020 19:22:29

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-09T12:22:25', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '1ad4a140-660e-4296-90f7-8e3edc171034' User entered '09 Oct 2020 12:22'	System	09 Oct 2020 19:22:29
	System	09 Oct 2020 19:22:29

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	07 Oct 2020 15:08:51
User entered 'Day 8'	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-09T00:55:51', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ef686fe8-bb88-4976-b42f-50310fe5afaf'	System	09 Oct 2020 07:55:56
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 07:55:56

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-09T00:55:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ef686fe8-bb88-4976-b42f-50310fe5afaf' User entered '09 Oct 2020 00:55'	System	09 Oct 2020 07:55:56
	System	09 Oct 2020 07:55:56

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 15:08:51

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	08 Oct 2020 14:33:03
User entered 'Day 9'	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-09T12:22:47', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c30a0cfd-ffb6-43fb-9c3d-ce141c422405'	System	09 Oct 2020 19:22:53
User entered 'None (1)'	System	09 Oct 2020 19:22:53

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-10-09T12:22:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c30a0cfd-ffb6-43fb-9c3d-ce141c422405' User entered '09 Oct 2020 12:22'	System	09 Oct 2020 19:22:53
	System	09 Oct 2020 19:22:53

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:33:03

US3682178

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:33:03

US3682178

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Oct 2020 18:34:14

US3682178

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '8 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Oct 2020 18:34:14

US3682178

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Oct 2020 18:34:14

US3682178

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	Susan Reed (b) (4)	08 Oct 2020 18:34:14

US3682178

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Oct 2020 18:34:18

US3682178

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	08 Oct 2020 18:34:18

US3682178

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	Susan Reed (b) (4)	15 Oct 2020 18:05:16

US3682178

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '15 Oct 2020'	Susan Reed (b) (4)	15 Oct 2020 18:05:16

US3682178

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Oct 2020 18:05:16

US3682178

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	Susan Reed (b) (4)	15 Oct 2020 18:05:16

US3682178

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Oct 2020 18:05:19

US3682178

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	15 Oct 2020 18:05:19

US3682178

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	22 Oct 2020 18:23:20

US3682178

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '22 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	22 Oct 2020 18:23:20

US3682178

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	22 Oct 2020 18:23:20

US3682178

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	Susan Reed (b) (4)	22 Oct 2020 18:23:20

US3682178

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4)	22 Oct 2020 18:23:32

US3682178

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	22 Oct 2020 18:23:32

US3682178

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	03 Nov 2020 23:47:30

US3682178

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '03 Nov 2020'	(b) (4) Schuyler Thomas (b) (4)	03 Nov 2020 23:47:30

US3682178

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Clinic (Clinic)'	(b) (4) Schuyler Thomas (b) (4)	03 Nov 2020 23:47:30

US3682178

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'VISIT2'	System	03 Nov 2020 23:47:30

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User accepted default value 'Pre-Dose (PREDOSE)'	Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '03 Nov 2020'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '15:38'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '03 Nov 2020 15:38'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:06:19
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Schuyler Thomas (b) (4) (b) (4)	04 Nov 2020 01:05:07
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Nov 2020 01:04:03
User entered '96.6' F	Schuyler Thomas (b) (4) (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '75'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'bpm'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '12'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'breaths/min'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '113'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '72'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User accepted default value 'Post-Dose (POSTDOSE)'	Schuyler Thomas (b) (4) (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '03 Nov 2020'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16:49'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '03 Nov 2020 16:49'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '98.3' F	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '61'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'bpm'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '12'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'breaths/min'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '117'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '68'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	04 Nov 2020 01:04:03

US3682178

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4)	03 Nov 2020 23:52:02

US3682178

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '3 Nov 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	03 Nov 2020 23:52:02

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:05:26

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '03 Nov 2020'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:05:26

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Urine (URINE)'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:05:26

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Negative (NEGATIVE)'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:05:26

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	Schuyler Thomas (b) (4)	04 Nov 2020 01:05:26

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:05:26

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 01:05:26

US3682178

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered empty.	System	04 Nov 2020 01:05:26

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4) (b) (4)	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'MRNA-1273 OR PLACEBO'	System	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '03 Nov 2020'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16:17'	(b) (4) Schuyler Thomas (b) (4)	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '03 Nov 2020 16:17'	System	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Right Arm (RIGHT ARM)'	Schuyler Thomas (b) (4)	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'ONCE'	System	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'INTRAMUSCULAR'	System	04 Nov 2020 00:21:35

US3682178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 01:14:15

US3682178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 01:14:15

US3682178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16:08'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 01:14:15

US3682178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '03 Nov 2020 16:08'	System	04 Nov 2020 01:14:15

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:05:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:05:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '16:10'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '03 Nov 2020 16:10'	System	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered empty.	System	04 Nov 2020 01:14:34

US3682178

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	03 Nov 2020 23:47:37

US3682178

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	03 Nov 2020 23:47:37

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:51:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ca6d84dc-fe51-4d3e-a3a3-2af0d140db25'	System	04 Nov 2020 00:52:02
User entered 'Yes (Y)'	System	04 Nov 2020 00:52:02

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:51:49', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ca6d84dc-fe51-4d3e-a3a3-2af0d140db25' User entered '98.3'	System	04 Nov 2020 00:52:02
	System	04 Nov 2020 00:52:02

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:51:55', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ca6d84dc-fe51-4d3e-a3a3-2af0d140db25'	System	04 Nov 2020 00:52:02
User entered 'No (N)'	System	04 Nov 2020 00:52:02

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:51:59', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ca6d84dc-fe51-4d3e-a3a3-2af0d140db25'	System	04 Nov 2020 00:52:02
User entered '03 Nov 2020 16:51'	System	04 Nov 2020 00:52:02

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 16:37'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 19:07'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:37:26', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '6200dc85-2787-4669-a3f5-2d9b67e1e6c5' User entered 'Yes (Y)'	System	04 Nov 2020 05:37:42
	System	04 Nov 2020 05:37:42

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:37:35', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '6200dc85-2787-4669-a3f5-2d9b67e1e6c5' User entered '98.8'	System	04 Nov 2020 05:37:42
	System	04 Nov 2020 05:37:42

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:37:38', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '6200dc85-2787-4669-a3f5-2d9b67e1e6c5'	System	04 Nov 2020 05:37:42
User entered 'No (N)'	System	04 Nov 2020 05:37:42

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:37:41', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '6200dc85-2787-4669-a3f5-2d9b67e1e6c5'	System	04 Nov 2020 05:37:42
User entered '03 Nov 2020 21:37'	System	04 Nov 2020 05:37:42

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 20:02'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 2'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:47', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '57249d22-e28d-4296-b6d2-6d5b1f8cafae' User entered 'Yes (Y)'	System	05 Nov 2020 05:05:16
	System	05 Nov 2020 05:05:16

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '57249d22-e28d-4296-b6d2-6d5b1f8cafae' User entered '100.6'	System	05 Nov 2020 05:05:16
	System	05 Nov 2020 05:05:16

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:56', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '57249d22-e28d-4296-b6d2-6d5b1f8cafae' User entered 'Yes (Y)'	System	05 Nov 2020 05:05:16
	System	05 Nov 2020 05:05:16

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
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 'see con med sheet' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 09:22:23
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.'	Susan Reed (b) (4)	06 Nov 2020 01:04:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:05:04', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '57249d22-e28d-4296-b6d2-6d5b1f8cafae'	(b) (4)	
User entered '1'	System	05 Nov 2020 05:05:16
	System	05 Nov 2020 05:05:16
	System	05 Nov 2020 05:05:16

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'see conmed sheet' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 09:22:20
User opened query 'Per the participant response, medication was taken to prevent 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).	Susan Reed (b) (4)	06 Nov 2020 01:04:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:05:04', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '57249d22-e28d-4296-b6d2-6d5b1f8cafae'	(b) (4)	
User entered '1'	System	05 Nov 2020 05:05:16
	System	05 Nov 2020 05:05:16
	System	05 Nov 2020 05:05:16

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:05:13', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '57249d22-e28d-4296-b6d2-6d5b1f8cafae' User entered '04 Nov 2020 21:05'	System	05 Nov 2020 05:05:16
	System	05 Nov 2020 05:05:16

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 3'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '400dc016-7ee8-47ee-a418-5a6258578122' User entered 'Yes (Y)'	System	06 Nov 2020 08:01:22
	System	06 Nov 2020 08:01:22

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:56', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '400dc016-7ee8-47ee-a418-5a6258578122' User entered '98.2'	System	06 Nov 2020 08:01:22
	System	06 Nov 2020 08:01:22

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:01:08', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '400dc016-7ee8-47ee-a418-5a6258578122'	System	06 Nov 2020 08:01:22
User entered 'Yes (Y)'	System	06 Nov 2020 08:01:22

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
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 'see conmed sheet' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 04:53:25
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:01:18', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '400dc016-7ee8-47ee-a418-5a6258578122' User entered '1'	Susan Reed (b) (4) (b) (4)	06 Nov 2020 17:27:29
	System	06 Nov 2020 08:01:22
	System	06 Nov 2020 08:01:22
	System	06 Nov 2020 08:01:22

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:01:18', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '400dc016-7ee8-47ee-a418-5a6258578122' User entered '0'	System	06 Nov 2020 08:01:22
	System	06 Nov 2020 08:01:22

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:01:20', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '400dc016-7ee8-47ee-a418-5a6258578122' User entered '06 Nov 2020 00:01'	System	06 Nov 2020 08:01:22
	System	06 Nov 2020 08:01:22

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 4'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:26', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3c103cd2-a88a-44fb-b4a7-013dfd55d0ed' User entered 'Yes (Y)'	System	07 Nov 2020 05:00:45
	System	07 Nov 2020 05:00:45

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:39', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3c103cd2-a88a-44fb-b4a7-013dfd55d0ed' User entered '96.9'	System	07 Nov 2020 05:00:45
	System	07 Nov 2020 05:00:45

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:42', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3c103cd2-a88a-44fb-b4a7-013dfd55d0ed' User entered 'No (N)'	System	07 Nov 2020 05:00:45
	System	07 Nov 2020 05:00:45

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:44', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3c103cd2-a88a-44fb-b4a7-013dfd55d0ed' User entered '06 Nov 2020 21:00'	System	07 Nov 2020 05:00:45
	System	07 Nov 2020 05:00:45

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 5'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T00:37:58', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '52c46000-c86e-40b0-97f8-421f9a8659c0' User entered 'Yes (Y)'	System	08 Nov 2020 08:39:19
	System	08 Nov 2020 08:39:19

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T00:39:09', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '52c46000-c86e-40b0-97f8-421f9a8659c0' User entered '96.3'	System	08 Nov 2020 08:39:19
	System	08 Nov 2020 08:39:19

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T00:39:11', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '52c46000-c86e-40b0-97f8-421f9a8659c0' User entered 'No (N)'	System	08 Nov 2020 08:39:19
	System	08 Nov 2020 08:39:19

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T00:39:14', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '52c46000-c86e-40b0-97f8-421f9a8659c0' User entered '08 Nov 2020 00:39'	System	08 Nov 2020 08:39:19
	System	08 Nov 2020 08:39:19

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 6'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:16', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a24fe99b-cf82-4daa-8c69-74aa3fcf689c' User entered 'Yes (Y)'	System	09 Nov 2020 07:50:29
	System	09 Nov 2020 07:50:29

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:21', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a24fe99b-cf82-4daa-8c69-74aa3fcf689c' User entered '96.2'	System	09 Nov 2020 07:50:29
	System	09 Nov 2020 07:50:29

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:24', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a24fe99b-cf82-4daa-8c69-74aa3fcf689c' User entered 'No (N)'	System	09 Nov 2020 07:50:29
	System	09 Nov 2020 07:50:29

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:27', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a24fe99b-cf82-4daa-8c69-74aa3fcf689c'	System	09 Nov 2020 07:50:29
User entered '08 Nov 2020 23:50'	System	09 Nov 2020 07:50:29

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 7'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:32:20', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ca5609ed-c77e-46fa-a491-de4744d019c6' User entered 'Yes (Y)'	System	10 Nov 2020 08:32:33
	System	10 Nov 2020 08:32:33

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:32:24', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ca5609ed-c77e-46fa-a491-de4744d019c6' User entered '96.4'	System	10 Nov 2020 08:32:33
	System	10 Nov 2020 08:32:33

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:32:27', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ca5609ed-c77e-46fa-a491-de4744d019c6'	System	10 Nov 2020 08:32:33
User entered 'No (N)'	System	10 Nov 2020 08:32:33

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:32:29', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'ca5609ed-c77e-46fa-a491-de4744d019c6' User entered '10 Nov 2020 00:32'	System	10 Nov 2020 08:32:33
	System	10 Nov 2020 08:32:33

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:04', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b5a4b2dd-cfb2-45b2-9103-c746daa998a0' User entered 'None (1)'	System	04 Nov 2020 00:52:28
	System	04 Nov 2020 00:52:28

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:11', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b5a4b2dd-cfb2-45b2-9103-c746daa998a0' User entered 'No (N)'	System	04 Nov 2020 00:52:28
	System	04 Nov 2020 00:52:28

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:16', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b5a4b2dd-cfb2-45b2-9103-c746daa998a0' User entered 'No (N)'	System	04 Nov 2020 00:52:28
	System	04 Nov 2020 00:52:28

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:22', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b5a4b2dd-cfb2-45b2-9103-c746daa998a0' User entered 'None (1)'	System	04 Nov 2020 00:52:28
	System	04 Nov 2020 00:52:28

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:26', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b5a4b2dd-cfb2-45b2-9103-c746daa998a0' User entered '03 Nov 2020 16:52'	System	04 Nov 2020 00:52:28
	System	04 Nov 2020 00:52:28

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 16:37'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 19:07'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:36:27', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c972a4d6-717a-4468-9d3f-6585295009a1'	System	04 Nov 2020 05:37:24
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Nov 2020 05:37:24

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:36:36', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c972a4d6-717a-4468-9d3f-6585295009a1' User entered 'No (N)'	System	04 Nov 2020 05:37:24
	System	04 Nov 2020 05:37:24

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:37:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c972a4d6-717a-4468-9d3f-6585295009a1' User entered 'No (N)'	System	04 Nov 2020 05:37:24
	System	04 Nov 2020 05:37:24

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:37:12', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c972a4d6-717a-4468-9d3f-6585295009a1' User entered 'None (1)'	System	04 Nov 2020 05:37:24
	System	04 Nov 2020 05:37:24

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:37:19', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c972a4d6-717a-4468-9d3f-6585295009a1' User entered '03 Nov 2020 21:37'	System	04 Nov 2020 05:37:24
	System	04 Nov 2020 05:37:24

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 20:02'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 2'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:03:29', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cfd9e415-8631-4fc0-a1c0-84a2141eca86'	System	05 Nov 2020 05:03:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	05 Nov 2020 05:03:53

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:03:32', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cfd9e415-8631-4fc0-a1c0-84a2141eca86'	System	05 Nov 2020 05:03:53
User entered 'No (N)'	System	05 Nov 2020 05:03:53

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:03:35', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cfd9e415-8631-4fc0-a1c0-84a2141eca86'	System	05 Nov 2020 05:03:53
User entered 'No (N)'	System	05 Nov 2020 05:03:53

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:03:42', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cfd9e415-8631-4fc0-a1c0-84a2141eca86'	System	05 Nov 2020 05:03:53
User entered 'Does not interfere with activity (2)'	System	05 Nov 2020 05:03:53

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:03:49', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cfd9e415-8631-4fc0-a1c0-84a2141eca86' User entered '04 Nov 2020 21:03'	System	05 Nov 2020 05:03:53
	System	05 Nov 2020 05:03:53

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 3'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:24', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3cfb5273-18e4-4245-a8c0-9f08ff108857'	System	06 Nov 2020 08:00:39
User entered 'Does not interfere with activity (2)'	System	06 Nov 2020 08:00:39

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:27', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3cfb5273-18e4-4245-a8c0-9f08ff108857' User entered 'No (N)'	System	06 Nov 2020 08:00:39
	System	06 Nov 2020 08:00:39

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:29', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3cfb5273-18e4-4245-a8c0-9f08ff108857' User entered 'No (N)'	System	06 Nov 2020 08:00:39
	System	06 Nov 2020 08:00:39

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:32', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3cfb5273-18e4-4245-a8c0-9f08ff108857'	System	06 Nov 2020 08:00:39
User entered 'Does not interfere with activity (2)'	System	06 Nov 2020 08:00:39

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:37', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3cfb5273-18e4-4245-a8c0-9f08ff108857'	System	06 Nov 2020 08:00:39
User entered '06 Nov 2020 00:00'	System	06 Nov 2020 08:00:39

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 4'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:06', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3677fa8-9fc5-477a-b538-6efaaba7153c'	System	07 Nov 2020 05:00:22
User entered 'None (1)'	System	07 Nov 2020 05:00:22

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:08', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3677fa8-9fc5-477a-b538-6efaaba7153c' User entered 'No (N)'	System	07 Nov 2020 05:00:22
	System	07 Nov 2020 05:00:22

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:10', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3677fa8-9fc5-477a-b538-6efaaba7153c' User entered 'No (N)'	System	07 Nov 2020 05:00:22
	System	07 Nov 2020 05:00:22

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:16', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3677fa8-9fc5-477a-b538-6efaaba7153c'	System	07 Nov 2020 05:00:22
User entered 'Does not interfere with activity (2)'	System	07 Nov 2020 05:00:22

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:19', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3677fa8-9fc5-477a-b538-6efaaba7153c' User entered '06 Nov 2020 21:00'	System	07 Nov 2020 05:00:22
	System	07 Nov 2020 05:00:22

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 5'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:36', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '970d63a4-534c-4745-996e-debbfde8bfbf' User entered 'None (1)'	System	08 Nov 2020 07:59:52
	System	08 Nov 2020 07:59:52

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:38', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '970d63a4-534c-4745-996e-debbfde8bfbf'	System	08 Nov 2020 07:59:52
User entered 'No (N)'	System	08 Nov 2020 07:59:52

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:40', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '970d63a4-534c-4745-996e-debbfde8bfbf' User entered 'No (N)'	System	08 Nov 2020 07:59:52
	System	08 Nov 2020 07:59:52

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:46', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '970d63a4-534c-4745-996e-debbfde8bfbf'	System	08 Nov 2020 07:59:52
User entered 'None (1)'	System	08 Nov 2020 07:59:52

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '970d63a4-534c-4745-996e-debbfde8bfbf' User entered '07 Nov 2020 23:59'	System	08 Nov 2020 07:59:52
	System	08 Nov 2020 07:59:52

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 6'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:30', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7ecdba00-9594-4278-8626-1e246aeaa89e'	System	09 Nov 2020 07:50:42
User entered 'None (1)'	System	09 Nov 2020 07:50:42

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:32', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7ecdba00-9594-4278-8626-1e246aeaa89e' User entered 'No (N)'	System	09 Nov 2020 07:50:42
	System	09 Nov 2020 07:50:42

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:34', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7ecdba00-9594-4278-8626-1e246aeaa89e' User entered 'No (N)'	System	09 Nov 2020 07:50:42
	System	09 Nov 2020 07:50:42

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:36', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7ecdba00-9594-4278-8626-1e246aeaa89e' User entered 'None (1)'	System	09 Nov 2020 07:50:42
	System	09 Nov 2020 07:50:42

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:39', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7ecdba00-9594-4278-8626-1e246aeaa89e' User entered '08 Nov 2020 23:50'	System	09 Nov 2020 07:50:42
	System	09 Nov 2020 07:50:42

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 7'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:59', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd30c5a55-be11-4f4b-abaa-623da1ef3821'	System	10 Nov 2020 08:32:16
User entered 'None (1)'	System	10 Nov 2020 08:32:16

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:32:01', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd30c5a55-be11-4f4b-abaa-623da1ef3821' User entered 'No (N)'	System	10 Nov 2020 08:32:16
	System	10 Nov 2020 08:32:16

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:32:08', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd30c5a55-be11-4f4b-abaa-623da1ef3821' User entered 'No (N)'	System	10 Nov 2020 08:32:16
	System	10 Nov 2020 08:32:16

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:32:10', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd30c5a55-be11-4f4b-abaa-623da1ef3821'	System	10 Nov 2020 08:32:16
User entered 'None (1)'	System	10 Nov 2020 08:32:16

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:32:13', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd30c5a55-be11-4f4b-abaa-623da1ef3821' User entered '10 Nov 2020 00:32'	System	10 Nov 2020 08:32:16
	System	10 Nov 2020 08:32:16

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '23698388-c0d3-4135-86ec-2b2dec7a2e41' User entered 'None (0)'	System	04 Nov 2020 00:52:54
	System	04 Nov 2020 00:52:54

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:33', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '23698388-c0d3-4135-86ec-2b2dec7a2e41' User entered 'None (0)'	System	04 Nov 2020 00:52:54
	System	04 Nov 2020 00:52:54

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:35', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '23698388-c0d3-4135-86ec-2b2dec7a2e41' User entered 'None (0)'	System	04 Nov 2020 00:52:54
	System	04 Nov 2020 00:52:54

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:37', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '23698388-c0d3-4135-86ec-2b2dec7a2e41' User entered 'None (0)'	System	04 Nov 2020 00:52:54
	System	04 Nov 2020 00:52:54

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:39', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '23698388-c0d3-4135-86ec-2b2dec7a2e41' User entered 'None (0)'	System	04 Nov 2020 00:52:54
	System	04 Nov 2020 00:52:54

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:41', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '23698388-c0d3-4135-86ec-2b2dec7a2e41' User entered 'None (0)'	System	04 Nov 2020 00:52:54
	System	04 Nov 2020 00:52:54

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:46', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '23698388-c0d3-4135-86ec-2b2dec7a2e41'	System	04 Nov 2020 00:52:54
User entered 'No (N)'	System	04 Nov 2020 00:52:54

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T16:52:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '23698388-c0d3-4135-86ec-2b2dec7a2e41'	System	04 Nov 2020 00:52:54
User entered '03 Nov 2020 16:52'	System	04 Nov 2020 00:52:54

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 16:37'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 19:07'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:35:47', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91047735-3ff8-45b3-9d2d-6b929ab57bff' User entered 'None (0)'	System	04 Nov 2020 05:36:18
	System	04 Nov 2020 05:36:18

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:35:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91047735-3ff8-45b3-9d2d-6b929ab57bff' User entered 'None (0)'	System	04 Nov 2020 05:36:18
	System	04 Nov 2020 05:36:18

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:35:58', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91047735-3ff8-45b3-9d2d-6b929ab57bff' User entered 'None (0)'	System	04 Nov 2020 05:36:18
	System	04 Nov 2020 05:36:18

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:36:04', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91047735-3ff8-45b3-9d2d-6b929ab57bff'	System	04 Nov 2020 05:36:18
User entered 'No interference with activity (1)'	System	04 Nov 2020 05:36:18

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:36:06', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91047735-3ff8-45b3-9d2d-6b929ab57bff' User entered 'None (0)'	System	04 Nov 2020 05:36:18
	System	04 Nov 2020 05:36:18

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:36:09', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91047735-3ff8-45b3-9d2d-6b929ab57bff' User entered 'None (0)'	System	04 Nov 2020 05:36:18
	System	04 Nov 2020 05:36:18

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:36:11', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91047735-3ff8-45b3-9d2d-6b929ab57bff'	System	04 Nov 2020 05:36:18
User entered 'No (N)'	System	04 Nov 2020 05:36:18

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-03T21:36:16', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '91047735-3ff8-45b3-9d2d-6b929ab57bff'	System	04 Nov 2020 05:36:18
User entered '03 Nov 2020 21:36'	System	04 Nov 2020 05:36:18

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '03 Nov 2020 20:02'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 2'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:07', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c2178329-e057-46b9-a7a5-03645ea7af1e'	System	05 Nov 2020 05:04:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Nov 2020 05:04:41

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:10', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c2178329-e057-46b9-a7a5-03645ea7af1e'	System	05 Nov 2020 05:04:41
User entered 'Some interference with activity (2)'	System	05 Nov 2020 05:04:41

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:16', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c2178329-e057-46b9-a7a5-03645ea7af1e'	System	05 Nov 2020 05:04:41
User entered 'Some interference with activity (2)'	System	05 Nov 2020 05:04:41

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:18', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c2178329-e057-46b9-a7a5-03645ea7af1e'	System	05 Nov 2020 05:04:41
User entered 'Some interference with activity (2)'	System	05 Nov 2020 05:04:41

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:21', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c2178329-e057-46b9-a7a5-03645ea7af1e' User entered 'None (0)'	System	05 Nov 2020 05:04:41
	System	05 Nov 2020 05:04:41

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:27', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c2178329-e057-46b9-a7a5-03645ea7af1e'	System	05 Nov 2020 05:04:41
User entered 'Some interference with activity not requiring medical attention (2)'	System	05 Nov 2020 05:04:41

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:30', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c2178329-e057-46b9-a7a5-03645ea7af1e' User entered 'No (N)'	System	05 Nov 2020 05:04:41
	System	05 Nov 2020 05:04:41

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-04T21:04:37', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'c2178329-e057-46b9-a7a5-03645ea7af1e' User entered '04 Nov 2020 21:04'	System	05 Nov 2020 05:04:41
	System	05 Nov 2020 05:04:41

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 3'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-05T23:59:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3f76c9bf-ba92-4f3d-9b6f-f35f3ceaef14'	System	06 Nov 2020 08:00:21
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Nov 2020 08:00:21

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-05T23:59:46', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3f76c9bf-ba92-4f3d-9b6f-f35f3ceaf14'	System	06 Nov 2020 08:00:21
User entered 'No interference with activity (1)'	System	06 Nov 2020 08:00:21

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-05T23:59:48', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3f76c9bf-ba92-4f3d-9b6f-f35f3ceaef14'	System	06 Nov 2020 08:00:21
User entered 'None (0)'	System	06 Nov 2020 08:00:21

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-05T23:59:52', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3f76c9bf-ba92-4f3d-9b6f-f35f3ceaef14' User entered 'None (0)'	System	06 Nov 2020 08:00:21
	System	06 Nov 2020 08:00:21

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:02', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3f76c9bf-ba92-4f3d-9b6f-f35f3ceaf14'	System	06 Nov 2020 08:00:21
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	06 Nov 2020 08:00:21

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:05', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3f76c9bf-ba92-4f3d-9b6f-f35f3ceaf14'	System	06 Nov 2020 08:00:21
User entered 'None (0)'	System	06 Nov 2020 08:00:21

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:08', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3f76c9bf-ba92-4f3d-9b6f-f35f3ceaef14'	System	06 Nov 2020 08:00:21
User entered 'Yes (Y)'	System	06 Nov 2020 08:00:21

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T00:00:18', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3f76c9bf-ba92-4f3d-9b6f-f35f3ceaf14'	System	06 Nov 2020 08:00:21
User entered '06 Nov 2020 00:00'	System	06 Nov 2020 08:00:21

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 4'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T20:59:39', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e769cf44-3c13-411d-802c-2036206dd7f0'	System	07 Nov 2020 05:00:06
User entered 'None (0)'	System	07 Nov 2020 05:00:06

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T20:59:41', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e769cf44-3c13-411d-802c-2036206dd7f0'	System	07 Nov 2020 05:00:06
User entered 'None (0)'	System	07 Nov 2020 05:00:06

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T20:59:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e769cf44-3c13-411d-802c-2036206dd7f0' User entered 'None (0)'	System	07 Nov 2020 05:00:06
	System	07 Nov 2020 05:00:06

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T20:59:46', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e769cf44-3c13-411d-802c-2036206dd7f0' User entered 'None (0)'	System	07 Nov 2020 05:00:06
	System	07 Nov 2020 05:00:06

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T20:59:48', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e769cf44-3c13-411d-802c-2036206dd7f0'	System	07 Nov 2020 05:00:06
User entered 'None (0)'	System	07 Nov 2020 05:00:06

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T20:59:55', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e769cf44-3c13-411d-802c-2036206dd7f0' User entered 'None (0)'	System	07 Nov 2020 05:00:06
	System	07 Nov 2020 05:00:06

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T20:59:58', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e769cf44-3c13-411d-802c-2036206dd7f0'	System	07 Nov 2020 05:00:06
User entered 'No (N)'	System	07 Nov 2020 05:00:06

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-06T21:00:01', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e769cf44-3c13-411d-802c-2036206dd7f0'	System	07 Nov 2020 05:00:06
User entered '06 Nov 2020 21:00'	System	07 Nov 2020 05:00:06

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 5'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:17', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd830fb06-987a-4c87-917b-62375bd70e5b' User entered 'None (0)'	System	08 Nov 2020 07:59:36
	System	08 Nov 2020 07:59:36

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:19', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd830fb06-987a-4c87-917b-62375bd70e5b' User entered 'None (0)'	System	08 Nov 2020 07:59:36
	System	08 Nov 2020 07:59:36

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:21', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd830fb06-987a-4c87-917b-62375bd70e5b' User entered 'None (0)'	System	08 Nov 2020 07:59:36
	System	08 Nov 2020 07:59:36

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:22', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd830fb06-987a-4c87-917b-62375bd70e5b' User entered 'None (0)'	System	08 Nov 2020 07:59:36
	System	08 Nov 2020 07:59:36

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:24', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd830fb06-987a-4c87-917b-62375bd70e5b' User entered 'None (0)'	System	08 Nov 2020 07:59:36
	System	08 Nov 2020 07:59:36

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:26', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd830fb06-987a-4c87-917b-62375bd70e5b' User entered 'None (0)'	System	08 Nov 2020 07:59:36
	System	08 Nov 2020 07:59:36

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:29', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd830fb06-987a-4c87-917b-62375bd70e5b' User entered 'No (N)'	System	08 Nov 2020 07:59:36
	System	08 Nov 2020 07:59:36

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-07T23:59:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd830fb06-987a-4c87-917b-62375bd70e5b' User entered '07 Nov 2020 23:59'	System	08 Nov 2020 07:59:36
	System	08 Nov 2020 07:59:36

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 6'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7e6b4ea4-3028-4de2-987d-8035e3e85272' User entered 'None (0)'	System	09 Nov 2020 07:50:59
	System	09 Nov 2020 07:50:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:45', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7e6b4ea4-3028-4de2-987d-8035e3e85272' User entered 'None (0)'	System	09 Nov 2020 07:50:59
	System	09 Nov 2020 07:50:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:47', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7e6b4ea4-3028-4de2-987d-8035e3e85272' User entered 'None (0)'	System	09 Nov 2020 07:50:59
	System	09 Nov 2020 07:50:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:49', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7e6b4ea4-3028-4de2-987d-8035e3e85272' User entered 'None (0)'	System	09 Nov 2020 07:50:59
	System	09 Nov 2020 07:50:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7e6b4ea4-3028-4de2-987d-8035e3e85272' User entered 'None (0)'	System	09 Nov 2020 07:50:59
	System	09 Nov 2020 07:50:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:52', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7e6b4ea4-3028-4de2-987d-8035e3e85272' User entered 'None (0)'	System	09 Nov 2020 07:50:59
	System	09 Nov 2020 07:50:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7e6b4ea4-3028-4de2-987d-8035e3e85272'	System	09 Nov 2020 07:50:59
User entered 'No (N)'	System	09 Nov 2020 07:50:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-08T23:50:57', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7e6b4ea4-3028-4de2-987d-8035e3e85272' User entered '08 Nov 2020 23:50'	System	09 Nov 2020 07:50:59
	System	09 Nov 2020 07:50:59

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
Data entry locked.	System	04 Nov 2020 00:21:35
User entered 'Day 7'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:37', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd9bcab06-4930-49d8-813f-4b4240c47aaf' User entered 'None (0)'	System	10 Nov 2020 08:31:57
	System	10 Nov 2020 08:31:57

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:39', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd9bcab06-4930-49d8-813f-4b4240c47aaf' User entered 'None (0)'	System	10 Nov 2020 08:31:57
	System	10 Nov 2020 08:31:57

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:41', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd9bcab06-4930-49d8-813f-4b4240c47aaf' User entered 'None (0)'	System	10 Nov 2020 08:31:57
	System	10 Nov 2020 08:31:57

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd9bcab06-4930-49d8-813f-4b4240c47aaf' User entered 'None (0)'	System	10 Nov 2020 08:31:57
	System	10 Nov 2020 08:31:57

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:45', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd9bcab06-4930-49d8-813f-4b4240c47aaf' User entered 'None (0)'	System	10 Nov 2020 08:31:57
	System	10 Nov 2020 08:31:57

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:46', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd9bcab06-4930-49d8-813f-4b4240c47aaf' User entered 'None (0)'	System	10 Nov 2020 08:31:57
	System	10 Nov 2020 08:31:57

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:50', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd9bcab06-4930-49d8-813f-4b4240c47aaf' User entered 'No (N)'	System	10 Nov 2020 08:31:57
	System	10 Nov 2020 08:31:57

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-11-10T00:31:55', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'd9bcab06-4930-49d8-813f-4b4240c47aaf' User entered '10 Nov 2020 00:31'	System	10 Nov 2020 08:31:57
	System	10 Nov 2020 08:31:57

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 00:21:35

US3682178

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:05:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:42:36
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 00:21:35

US3682178

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	Susan Reed (b) (4)	12 Nov 2020 19:34:10

US3682178

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered '12 Nov 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:34:10

US3682178

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:34:10

US3682178

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:34:10

US3682178

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:21:11
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:34:14

US3682178

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	12 Nov 2020 19:34:14

US3682178

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	19 Nov 2020 23:27:17

US3682178

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '19 Nov 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	19 Nov 2020 23:27:17

US3682178

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	19 Nov 2020 23:27:17

US3682178

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	19 Nov 2020 23:27:17

US3682178

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	19 Nov 2020 23:27:25

US3682178

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	19 Nov 2020 23:27:25

US3682178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	25 Nov 2020 22:14:57

US3682178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '24 Nov 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	25 Nov 2020 22:14:57

US3682178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	25 Nov 2020 22:14:57

US3682178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	Susan Reed (b) (4)	25 Nov 2020 22:14:57

US3682178

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:00:29

US3682178

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	24 Nov 2020 19:00:29

US3682178

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	01 Dec 2020 23:54:55

US3682178

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Dec 2020'	(b) (4) Schuyler Thomas (b) (4)	01 Dec 2020 23:54:55

US3682178

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Clinic (Clinic)'	(b) (4) Schuyler Thomas (b) (4) (b) (4)	01 Dec 2020 23:54:55

US3682178

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'VISIT3'	System	01 Dec 2020 23:54:55

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Dec 2020'	(b) (4) Schuyler Thomas (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '15:30'	(b) (4) Schuyler Thomas (b) (4) (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '01 Dec 2020 15:30'	System	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '97.6' F	(b) (4) Schuyler Thomas (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '65'	(b) (4) Schuyler Thomas (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'bpm'	System	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '12'	(b) (4) Schuyler Thomas (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'breaths/min'	System	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '94'	(b) (4) Schuyler Thomas (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 10:26:27
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).	Schuyler Thomas (b) (4) (b) (4)	02 Dec 2020 00:24:15
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).		02 Dec 2020 00:22:35
User entered '58'	Schuyler Thomas (b) (4) (b) (4)	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'mmHg'	System	02 Dec 2020 00:22:35

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03

US3682178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03

US3682178

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	01 Dec 2020 23:55:10

US3682178

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Dec 2020'	(b) (4) Schuyler Thomas (b) (4)	01 Dec 2020 23:55:10

US3682178

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 01:17:17

US3682178

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 01:17:17

US3682178

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered '15:44'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 01:17:17

US3682178

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered '01 Dec 2020 15:44'	System	02 Dec 2020 01:17:17

US3682178

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:31:21
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	01 Dec 2020 23:55:00

US3682178

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	01 Dec 2020 23:55:00

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-01T12:25:26', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eb834fa5-1d20-4803-899d-23f533087d4e' User entered 'No (N)'	System	01 Dec 2020 20:25:39
	System	01 Dec 2020 20:25:39

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-01T12:25:29', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eb834fa5-1d20-4803-899d-23f533087d4e'	System	01 Dec 2020 20:25:39
User entered 'No (N)'	System	01 Dec 2020 20:25:39

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-01T12:25:36', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eb834fa5-1d20-4803-899d-23f533087d4e' User entered '01 Dec 2020 12:25:36'	System	01 Dec 2020 20:25:39
	System	01 Dec 2020 20:25:39

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-07T15:45:51', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a8b586ff-1888-43e5-82f0-cad867c59a63'	System	07 Dec 2020 23:46:01
User entered 'No (N)'	System	07 Dec 2020 23:46:01

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-07T15:45:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a8b586ff-1888-43e5-82f0-cad867c59a63'	System	07 Dec 2020 23:46:01
User entered 'No (N)'	System	07 Dec 2020 23:46:01

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-07T15:45:58', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'a8b586ff-1888-43e5-82f0-cad867c59a63' User entered '07 Dec 2020 15:45:58'	System	07 Dec 2020 23:46:01
	System	07 Dec 2020 23:46:01

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-14T12:01:23', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'bc007a8e-b367-445c-ba5c-42a6a1546552'	System	14 Dec 2020 20:03:59
User entered 'No (N)'	System	14 Dec 2020 20:03:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-14T12:01:25', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'bc007a8e-b367-445c-ba5c-42a6a1546552'	System	14 Dec 2020 20:03:59
User entered 'No (N)'	System	14 Dec 2020 20:03:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-14T12:01:28', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'bc007a8e-b367-445c-ba5c-42a6a1546552' User entered '14 Dec 2020 12:01:28'	System	14 Dec 2020 20:03:59
	System	14 Dec 2020 20:03:59

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-19T00:01:17', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '385624d4-16da-4de2-a31a-80940e6030d1'	System	19 Dec 2020 08:01:28
User entered 'No (N)'	System	19 Dec 2020 08:01:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-19T00:01:21', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '385624d4-16da-4de2-a31a-80940e6030d1'	System	19 Dec 2020 08:01:28
User entered 'No (N)'	System	19 Dec 2020 08:01:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-19T00:01:24', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '385624d4-16da-4de2-a31a-80940e6030d1' User entered '19 Dec 2020 00:01:24'	System	19 Dec 2020 08:01:28
	System	19 Dec 2020 08:01:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-26T00:01:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '1c1a6e18-c77b-4d34-a7ab-7efa7f04b74b' User entered 'No (N)'	System	26 Dec 2020 08:01:47
	System	26 Dec 2020 08:01:47

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-26T00:01:36', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '1c1a6e18-c77b-4d34-a7ab-7efa7f04b74b' User entered 'No (N)'	System	26 Dec 2020 08:01:47
	System	26 Dec 2020 08:01:47

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2020-12-26T00:01:43', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '1c1a6e18-c77b-4d34-a7ab-7efa7f04b74b' User entered '26 Dec 2020 00:01:43'	System	26 Dec 2020 08:01:47
	System	26 Dec 2020 08:01:47

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-02T00:24:36', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'f4a2de36-5bd4-4d42-b3a9-c3d5fdf4e8db'	System	02 Jan 2021 08:24:49
User entered 'No (N)'	System	02 Jan 2021 08:24:49

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-02T00:24:41', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'f4a2de36-5bd4-4d42-b3a9-c3d5fdf4e8db'	System	02 Jan 2021 08:24:49
User entered 'No (N)'	System	02 Jan 2021 08:24:49

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-02T00:24:44', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'f4a2de36-5bd4-4d42-b3a9-c3d5fdf4e8db' User entered '02 Jan 2021 00:24:44'	System	02 Jan 2021 08:24:49
	System	02 Jan 2021 08:24:49

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-11T01:19:15', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '8e13a4e9-1f5e-4321-8851-aec4181bc900'	System	11 Jan 2021 09:19:27
User entered 'No (N)'	System	11 Jan 2021 09:19:27

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-11T01:19:19', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '8e13a4e9-1f5e-4321-8851-aec4181bc900'	System	11 Jan 2021 09:19:27
User entered 'No (N)'	System	11 Jan 2021 09:19:27

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-11T01:19:23', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '8e13a4e9-1f5e-4321-8851-aec4181bc900'	System	11 Jan 2021 09:19:27
User entered '11 Jan 2021 01:19:23'	System	11 Jan 2021 09:19:27

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-16T07:18:05', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3813a1b9-6788-40c3-8605-bf8c964e8e97'	System	16 Jan 2021 15:18:13
User entered 'No (N)'	System	16 Jan 2021 15:18:13

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-16T07:18:08', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3813a1b9-6788-40c3-8605-bf8c964e8e97'	System	16 Jan 2021 15:18:13
User entered 'No (N)'	System	16 Jan 2021 15:18:13

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-16T07:18:11', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3813a1b9-6788-40c3-8605-bf8c964e8e97' User entered '16 Jan 2021 07:18:11'	System	16 Jan 2021 15:18:13
	System	16 Jan 2021 15:18:13

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-23T02:59:30', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '66f24625-ea4f-4955-8265-379a2302e0d1' User entered 'No (N)'	System	23 Jan 2021 10:59:39
	System	23 Jan 2021 10:59:39

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-23T02:59:33', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '66f24625-ea4f-4955-8265-379a2302e0d1' User entered 'No (N)'	System	23 Jan 2021 10:59:39

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-23T02:59:36', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '66f24625-ea4f-4955-8265-379a2302e0d1' User entered '23 Jan 2021 02:59:36'	System	23 Jan 2021 10:59:39
	System	23 Jan 2021 10:59:39

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-31T13:10:35', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7af96bd1-e347-451a-b737-e89ab10c8499'	System	31 Jan 2021 21:10:46
User entered 'No (N)'	System	31 Jan 2021 21:10:46

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-31T13:10:38', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7af96bd1-e347-451a-b737-e89ab10c8499'	System	31 Jan 2021 21:10:46
User entered 'No (N)'	System	31 Jan 2021 21:10:46

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-01-31T13:10:41', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '7af96bd1-e347-451a-b737-e89ab10c8499' User entered '31 Jan 2021 13:10:41'	System	31 Jan 2021 21:10:46
	System	31 Jan 2021 21:10:46

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-06T00:01:26', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b79a0595-d9c4-472e-a57c-38e7a7b27957'	System	06 Feb 2021 08:01:40
User entered 'No (N)'	System	06 Feb 2021 08:01:40

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-06T00:01:31', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b79a0595-d9c4-472e-a57c-38e7a7b27957'	System	06 Feb 2021 08:01:40
User entered 'No (N)'	System	06 Feb 2021 08:01:40

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-06T00:01:34', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b79a0595-d9c4-472e-a57c-38e7a7b27957'	System	06 Feb 2021 08:01:40
User entered '06 Feb 2021 00:01:34'	System	06 Feb 2021 08:01:40

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-13T07:39:51', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '10f6cb94-51c3-496c-afbd-7037075cbe90'	System	13 Feb 2021 15:40:00
User entered 'No (N)'	System	13 Feb 2021 15:40:00

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-13T07:39:54', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '10f6cb94-51c3-496c-afbd-7037075cbe90'	System	13 Feb 2021 15:40:00
User entered 'No (N)'	System	13 Feb 2021 15:40:00

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-13T07:39:58', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '10f6cb94-51c3-496c-afbd-7037075cbe90'	System	13 Feb 2021 15:40:00
User entered '13 Feb 2021 07:39:58'	System	13 Feb 2021 15:40:00

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-21T21:34:19', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eb096877-14f5-4d6a-bc6e-709161fc6a9d' User entered 'No (N)'	System	22 Feb 2021 05:34:26

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-21T21:34:21', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eb096877-14f5-4d6a-bc6e-709161fc6a9d' User entered 'No (N)'	System	22 Feb 2021 05:34:26

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-02-21T21:34:24', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eb096877-14f5-4d6a-bc6e-709161fc6a9d' User entered '21 Feb 2021 21:34:24'	System	22 Feb 2021 05:34:26
	System	22 Feb 2021 05:34:26

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-03T15:01:43-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b5e44e9c-4a97-43dc-b0d0-dbbfe91b7926'	System	03 Mar 2021 23:05:53
User entered 'No (N)'	System	03 Mar 2021 23:05:53

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-03T15:01:23-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b5e44e9c-4a97-43dc-b0d0-dbbfe91b7926'	System	03 Mar 2021 23:05:53
User entered 'No (N)'	System	03 Mar 2021 23:05:53

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-03T15:01:54-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b5e44e9c-4a97-43dc-b0d0-dbbfe91b7926'	System	03 Mar 2021 23:05:53
User entered '03 Mar 2021 15:01:54'	System	03 Mar 2021 23:05:53

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-08T12:00:44-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '339e132f-f142-4ef3-a22a-afa79fbc42d0'	System	08 Mar 2021 20:02:04
User entered 'Yes (Y)'	System	08 Mar 2021 20:02:04

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-08T12:00:48-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '339e132f-f142-4ef3-a22a-afa79fbc42d0'	System	08 Mar 2021 20:02:04
User entered 'No (N)'	System	08 Mar 2021 20:02:04

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-08T12:00:50-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '339e132f-f142-4ef3-a22a-afa79fbc42d0'	System	08 Mar 2021 20:02:04
User entered 'No (N)'	System	08 Mar 2021 20:02:04

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-08T12:00:57-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '339e132f-f142-4ef3-a22a-afa79fbc42d0'	System	08 Mar 2021 20:02:04
User entered 'Yes (Y)'	System	08 Mar 2021 20:02:04

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-08T12:01:24-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '339e132f-f142-4ef3-a22a-afa79fbc42d0'	System	08 Mar 2021 20:02:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Mar 2021 20:02:04

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-08T12:01:35-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '339e132f-f142-4ef3-a22a-afa79fbc42d0'	System	08 Mar 2021 20:02:04
User entered '08 Mar 2021 12:01:35'	System	08 Mar 2021 20:02:04

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-13T18:59:42-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '1ff5aea9-c476-4ab6-b21f-5a7099d4c42b'	System	14 Mar 2021 02:59:54
User entered 'No (N)'	System	14 Mar 2021 02:59:54

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-13T18:59:44-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '1ff5aea9-c476-4ab6-b21f-5a7099d4c42b'	System	14 Mar 2021 02:59:54
User entered 'No (N)'	System	14 Mar 2021 02:59:54

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-13T18:59:48-08:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '1ff5aea9-c476-4ab6-b21f-5a7099d4c42b' User entered '13 Mar 2021 18:59:48'	System	14 Mar 2021 02:59:54
	System	14 Mar 2021 02:59:54

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-20T10:42:06-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '4cde7537-1dc0-4620-85a1-736ea65c4ef3'	System	20 Mar 2021 17:42:15
User entered 'No (N)'	System	20 Mar 2021 17:42:15

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-20T10:42:08-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '4cde7537-1dc0-4620-85a1-736ea65c4ef3'	System	20 Mar 2021 17:42:15
User entered 'No (N)'	System	20 Mar 2021 17:42:15

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-20T10:42:12-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '4cde7537-1dc0-4620-85a1-736ea65c4ef3'	System	20 Mar 2021 17:42:15
User entered '20 Mar 2021 10:42:12'	System	20 Mar 2021 17:42:15

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-29T12:00:45-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eed23b1-b6e1-445c-ae0e-1011921753c8'	System	29 Mar 2021 19:01:21
User entered 'No (N)'	System	29 Mar 2021 19:01:21

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-29T12:00:48-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eed23b1-b6e1-445c-ae0e-1011921753c8'	System	29 Mar 2021 19:01:21
User entered 'No (N)'	System	29 Mar 2021 19:01:21

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-03-29T12:00:51-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'eed23b1-b6e1-445c-ae0e-1011921753c8' User entered '29 Mar 2021 12:00:51'	System	29 Mar 2021 19:01:21
	System	29 Mar 2021 19:01:21

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-06T12:13:45-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3d7d2fb-dc1b-4289-983f-3d9979c4ee5b'	System	06 Apr 2021 19:14:28
User entered 'Yes (Y)'	System	06 Apr 2021 19:14:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-06T12:13:48-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3d7d2fb-dc1b-4289-983f-3d9979c4ee5b'	System	06 Apr 2021 19:14:28
User entered 'No (N)'	System	06 Apr 2021 19:14:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-06T12:13:51-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3d7d2fb-dc1b-4289-983f-3d9979c4ee5b'	System	06 Apr 2021 19:14:28
User entered 'No (N)'	System	06 Apr 2021 19:14:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-06T12:13:57-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3d7d2fb-dc1b-4289-983f-3d9979c4ee5b'	System	06 Apr 2021 19:14:28
User entered 'Yes (Y)'	System	06 Apr 2021 19:14:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-06T12:14:06-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3d7d2fb-dc1b-4289-983f-3d9979c4ee5b'	System	06 Apr 2021 19:14:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Apr 2021 19:14:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-06T12:14:17-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'b3d7d2fb-dc1b-4289-983f-3d9979c4ee5b'	System	06 Apr 2021 19:14:28
User entered '06 Apr 2021 12:14:17'	System	06 Apr 2021 19:14:28

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-12T12:07:08-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '4487341b-f9d8-48e8-aa33-601e4783cbf9' User entered 'No (N)'	System	12 Apr 2021 19:07:26
	System	12 Apr 2021 19:07:26

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-12T12:07:10-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '4487341b-f9d8-48e8-aa33-601e4783cbf9' User entered 'No (N)'	System	12 Apr 2021 19:07:26
	System	12 Apr 2021 19:07:26

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-12T12:07:13-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '4487341b-f9d8-48e8-aa33-601e4783cbf9'	System	12 Apr 2021 19:07:26
User entered '12 Apr 2021 12:07:13'	System	12 Apr 2021 19:07:26

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-19T12:18:10-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e576ac1e-4ce8-4268-8aea-e2fb931fe09e'	System	19 Apr 2021 19:18:19
User entered 'No (N)'	System	19 Apr 2021 19:18:19

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-19T12:18:12-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e576ac1e-4ce8-4268-8aea-e2fb931fe09e'	System	19 Apr 2021 19:18:19
User entered 'No (N)'	System	19 Apr 2021 19:18:19

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-19T12:18:15-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'e576ac1e-4ce8-4268-8aea-e2fb931fe09e'	System	19 Apr 2021 19:18:19
User entered '19 Apr 2021 12:18:15'	System	19 Apr 2021 19:18:19

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-24T22:25:15-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3288046c-1c66-4f72-9a87-cf486ed4c315' User entered 'No (N)'	System	25 Apr 2021 05:25:23
	System	25 Apr 2021 05:25:23

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-24T22:25:18-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3288046c-1c66-4f72-9a87-cf486ed4c315'	System	25 Apr 2021 05:25:23
User entered 'No (N)'	System	25 Apr 2021 05:25:23

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-04-24T22:25:22-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: '3288046c-1c66-4f72-9a87-cf486ed4c315'	System	25 Apr 2021 05:25:23
User entered '24 Apr 2021 22:25:22'	System	25 Apr 2021 05:25:23

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-05-01T14:53:57-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cad36bc7-2dc9-4516-a4c2-0850611ac968'	System	01 May 2021 21:54:09
User entered 'No (N)'	System	01 May 2021 21:54:09

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Have you been exposed to someone with 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 (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-05-01T14:54:00-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cad36bc7-2dc9-4516-a4c2-0850611ac968'	System	01 May 2021 21:54:09
User entered 'No (N)'	System	01 May 2021 21:54:09

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (560FDCA4-310F-4AF0-9871-0C3AAC984B0C)', Time: '2021-05-01T14:54:02-07:00', User OID: 'PatientReportedOutcome (US3682178)', ODM File OID: 'cad36bc7-2dc9-4516-a4c2-0850611ac968'	System	01 May 2021 21:54:09
User entered '01 May 2021 14:54:02'	System	01 May 2021 21:54:09

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 11:31:44

US3682178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:44
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 11:31:44

US3682178

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:17:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 04:37:31
User entered 'Yes (Y)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	29 Dec 2020 00:25:40
Query 'Data is required. Please complete.' answered with 'pending data' (Site from System).	Mitchell Stern (b) (4) (b) (4)	28 Dec 2020 19:45:23
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 19:45:11
User entered empty; reason for change Data Entry Error	Mitchell Stern (b) (4) (b) (4)	28 Dec 2020 19:45:11
User entered 'Yes (Y)'	Mitchell Stern (b) (4) (b) (4)	28 Dec 2020 19:44:16

US3682178

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:17:44
User entered '28 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Mitchell Stern (b) (4)	29 Dec 2020 00:25:40
User entered empty; reason for change Data Entry Error	(b) (4)	
	Mitchell Stern (b) (4)	28 Dec 2020 19:45:11
User entered '28 Dec 2020'	(b) (4)	
	Mitchell Stern (b) (4)	28 Dec 2020 19:44:16
	(b) (4)	

US3682178

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:17:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Mitchell Stern (b) (4)	29 Dec 2020 00:25:40
User entered empty; reason for change Data Entry	(b) (4)	
Error	Mitchell Stern (b) (4)	28 Dec 2020 19:45:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Mitchell Stern (b) (4)	28 Dec 2020 19:44:16
	(b) (4)	

US3682178

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:17:44
User entered empty.	Mitchell Stern (b) (4)	28 Dec 2020 19:44:16

US3682178

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:17:44
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	28 Dec 2020 19:44:20

US3682178

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:32:03
User entered 'I'	System	28 Dec 2020 19:44:20

US3682178

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Feb 2021 23:07:03

US3682178

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '1 Feb 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Feb 2021 23:07:03

US3682178

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Feb 2021 23:07:03

US3682178

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Feb 2021 23:07:03

US3682178

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Feb 2021 23:07:08

US3682178

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User entered 'I'	System	01 Feb 2021 23:07:08

US3682178

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	04 Mar 2021 19:19:35

US3682178

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '4 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	04 Mar 2021 19:19:35

US3682178

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4)	04 Mar 2021 19:19:35

US3682178

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	04 Mar 2021 19:19:35

US3682178

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	04 Mar 2021 19:19:41

US3682178

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User entered 'I'	System	04 Mar 2021 19:19:41

US3682178

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 18:17:35

US3682178

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '1 Apr 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 18:17:35

US3682178

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 18:17:35

US3682178

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:05:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 18:17:35

US3682178

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 18:18:03

US3682178

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:15:44
User entered 'I'	System	01 Apr 2021 18:18:03

US3682178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered 'Yes (Y)'	Schuyler Thomas (b) (4)	27 Apr 2021 23:15:08
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '27 Apr 2021'	Schuyler Thomas (b) (4)	27 Apr 2021 23:15:08
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
User entered 'Clinic (Clinic)'	(b) (4) Schuyler Thomas (b) (4) (b) (4)	27 Apr 2021 23:15:08

US3682178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	27 Apr 2021 23:15:08

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered 'Yes (Y)'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '27 Apr 2021'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '15:49'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
User entered '27 Apr 2021 15:49'	System	27 Apr 2021 23:19:33

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '97.9' F	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered 'Oral (Oral)'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered empty.	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '73'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Apr 2021 23:19:33

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '12'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Apr 2021 23:19:33

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '96'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Apr 2021 23:19:33

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '67'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:33
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Apr 2021 23:19:33

US3682178

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered 'Yes (Y)'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:46
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered '27 Apr 2021'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:46
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 00:33:08

US3682178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 00:33:08

US3682178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
User entered '15:59'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 00:33:08

US3682178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 15:59'	System	28 Apr 2021 00:33:08

US3682178

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	28 Apr 2021 22:10:35
	(b) (4)	
User entered 'Yes (Y)'	Schuyler Thomas (b) (4)	27 Apr 2021 23:19:53
	(b) (4)	

US3682178

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 23:19:53

US3682178

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

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	15 Jan 2021 23:24:17

US3682178

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

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '15 Jan 2021'	(b) (4) Simone Riley (b) (4) (b) (4)	15 Jan 2021 23:24:17

US3682178

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

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[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 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Clinic (Clinic)'	(b) (4) Simone Riley (b) (4) (b) (4)	15 Jan 2021 23:24:17

US3682178

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

Form: Visit Date

Generated On: 11 Aug 2021 23:05:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 23:24:17

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 19:04:48
User entered '6 Jan 2021' reason for change: Data Entry Error	Simone Riley (b) (4)	04 Feb 2021 19:04:48
User entered '15 Jan 2021'	(b) (4)	25 Jan 2021 21:59:46
	(b) (4), (b) (6)	25 Jan 2021 21:59:46
	(b) (4)	15 Jan 2021 23:43:42
	Simone Riley (b) (4)	15 Jan 2021 23:43:42
	(b) (4)	

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	08 Mar 2021 21:02:11
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 20:13:01

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	15 Jan 2021 23:43:42

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
Amendment Manager inserted this DataPoint.	Sandy MacNicoll (b) (4)	08 Mar 2021 21:02:11
	(b) (4)	
	System	06 Mar 2021 20:13:01

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '15 Jan 2021'	(b) (4) Simone Riley (b) (4) (b) (4)	15 Jan 2021 23:43:42

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Simone Riley (b) (4) (b) (4)	15 Jan 2021 23:43:42

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 15:46:37
User entered 'mRNA-1273 (mRNA-1273)'	Simone Riley (b) (4)	15 Jan 2021 23:43:42
	(b) (4)	

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 15:46:37
User entered 'mRNA-1273 (mRNA-1273)'	Simone Riley (b) (4)	15 Jan 2021 23:43:42
	(b) (4)	

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) Simone Riley (b) (4) (b) (4)	15 Jan 2021 23:43:42

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered empty.	System	15 Jan 2021 23:43:42

US3682178

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

Form: Unblinding

Generated On: 11 Aug 2021 23:05:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered empty.	System	15 Jan 2021 23:43:42

US3682178

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 00:33:33

US3682178

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 00:33:33

US3682178

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '15:40'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 00:33:33

US3682178

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '15 Jan 2021 15:40'	System	16 Jan 2021 00:33:33

US3682178

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:05:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 00:33:44

US3682178

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 00:33:44

US3682178

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:05:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '15:36'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 00:33:44

US3682178

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:05:19

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:39:09
User entered '15 Jan 2021 15:36'	System	16 Jan 2021 00:33:44

US3682178

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 23:05:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:03:08
User closed query 'Per DM CLR: Per Day 159 on Safety Follow-up Diary, 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)	31 Mar 2021 15:06:27
Query 'Per DM CLR: Per Day 159 on Safety Follow-up Diary, 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 'Pt reported having a positive urine pregnancy test for this safety alert. An AE for pregnancy was added to the AE section. However, the site was queried to remove this information in the AE section because it did not belong. A pregnancy safety form was previously completed and sent to the Moderana Safety Team.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	30 Mar 2021 16:40:54
User opened query 'Per DM CLR: Per Day 159 on Safety Follow-up Diary, 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)	26 Mar 2021 17:33:39
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	19 Mar 2021 21:19:28

US3682178

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 23:05:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 6; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:52:09
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 6; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	(b) (4), (b) (6)	12 Feb 2021 16:46:41
' answered with 'AE eCRF updated' (Site from DM).		
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 6; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	(b) (4), (b) (6)	08 Feb 2021 08:35:31
' (Site from DM).		
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:01:35

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Nov 2020 19:04:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:04:14
Data point term sent to Coder	System	24 Nov 2020 19:02:31
User entered 'Headache'	Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'No (N)'	(b) (4) Susan Reed (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'No (N)'	(b) (4) Susan Reed (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered '23 Nov 2020'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) Susan Reed (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	25 Nov 2020 22:15:40
	(b) (4)	
User entered 'Yes (Y)'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered '24 Nov 2020' reason for change: New Information	Susan Reed (b) (4)	25 Nov 2020 22:15:40
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Susan Reed (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) Susan Reed (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:02:27

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Susan Reed (b) (4)	24 Nov 2020 19:02:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Susan Reed (b) (4)	24 Nov 2020 19:02:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User closed query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 11:21:44
Query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	08 Dec 2020 17:26:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	08 Dec 2020 17:25:53
User opened query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 09:49:15
User entered 'None (NONE)'	Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:02:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

US3682178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered 'I'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Susan Reed (b) (4)	25 Nov 2020 22:15:40
New Information	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	24 Nov 2020 19:02:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:02:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 19:02:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 19:02:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site lymphadenopathy, LLT: Injection site lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4)	14 Mar 2021 15:42:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Mar 2021 15:42:39
User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 17:44:54
Data point term sent to Coder	System	10 Mar 2021 22:58:53
Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy.' answered with 'updated accordingly' (Site from DM).	Mitchell Stern (b) (4)	10 Mar 2021 22:58:43
Coding entries removed.	Mitchell Stern (b) (4)	10 Mar 2021 22:58:35
User entered 'Right UNDERARM lymphadenopathy, ipsilateral to injection site' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	10 Mar 2021 22:58:35
User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:24:26

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 16:47:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 16:47:47
Data point term sent to Coder	System	12 Feb 2021 16:46:44
User entered 'underarm gland swelling'	(b) (4), (b) (6) (b) (4)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Underarm Gland Swelling or Tenderness on 06 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:45:07
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Underarm Gland Swelling or Tenderness on 06 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated accordingly' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	10 Mar 2021 22:49:57
User entered '06 Oct 2020' reason for change: Per Query Resolution	Mitchell Stern (b) (4) (b) (4)	10 Mar 2021 22:49:50
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Underarm Gland Swelling or Tenderness on 06 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:24:40
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User entered empty.	System	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User entered empty.	System	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:19:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User entered '0'	System	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20
User entered '0'	System	12 Feb 2021 16:46:30

US3682178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:20

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:03:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1 Pain at Injection Site, Day 2 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches these information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 08:21:21
Query 'Per DM CLR: Per Diary Dose 2 Day 1 Pain at Injection Site, Day 2 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches these information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Per guidance from protocol team, Con Meds taken for post-vaccination symptoms within 7 days of vaccination are not recorded.' (Site from DM).	Jesse Clark (b) (4) (b) (4)	09 Feb 2021 00:29:47
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1 Pain at Injection Site, Day 2 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches these information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:49:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 23:43:11

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: TRI LEGEST FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 06:53:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 06:53:44
Data point term sent to Coder	System	01 Oct 2020 23:44:08
User entered "TRILEGEST"	(b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per DM CLR: Indication for medication is reported as CONTRACEPTION, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:26:27
Query 'Per DM CLR: Indication for medication is reported as CONTRACEPTION, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'update' (Site from DM).	Susan Reed (b) (4) (b) (4)	02 Dec 2020 00:07:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	02 Dec 2020 00:07:45
User opened query 'Per DM CLR: Indication for medication is reported as CONTRACEPTION, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:22:40
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'CONTRACEPTION'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)' reason for change: New Information	(b) (4) Jesse Clark (b) (4)	15 Jan 2021 23:59:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '1 Jan 2021' reason for change: New Information	(b) (4)	15 Jan 2021 23:59:08
User entered empty.	Jesse Clark (b) (4)	01 Oct 2020 23:43:49
	(b) (4), (b) (6)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User entered '1'	System	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User entered '1'	System	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:14
User entered '804 (804)'	System	01 Oct 2020 23:43:49

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Oct 2020 09:14:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 09:14:18
Data point term sent to Coder	System	06 Oct 2020 00:34:30
User entered 'Ibuprofen'	Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:27:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'This does not meet ae criteria' (Site from DM).	Susan Reed (b) (4) (b) (4)	02 Dec 2020 00:09:06

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:23:15
User entered 'Injection site pain, muscle aches'	Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '400'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'mg (mg)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'as needed (PRN)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Oral (ORAL)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 21:01:13
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Oct 2020 20:22:21
User entered '02 Oct 2020' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	06 Oct 2020 20:22:21
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Oct 2020 00:34:08
User entered empty.	Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)' reason for change: New Information	(b) (4) Susan Reed (b) (4)	08 Oct 2020 18:35:12
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '2 Oct 2020' reason for change: New Information	(b) (4) Susan Reed (b) (4)	08 Oct 2020 18:35:12
User entered empty.	Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per DM CLR: Was this medication taken for solicited event?=No, however INJECTION SITE PAIN, MUSCLE ACHES is Solicited Events per Protocol and reported in Diary (1-7 days SAR reporting) with corresponding dates. Please verify information and update eCRF accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:27:22
Query 'Per DM CLR: Was this medication taken for solicited event?=No, however INJECTION SITE PAIN, MUSCLE ACHES is Solicited Events per Protocol and reported in Diary (1-7 days SAR reporting) with corresponding dates. Please verify information and update eCRF accordingly.' answered with 'updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	02 Dec 2020 00:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	02 Dec 2020 00:08:55
User opened query 'Per DM CLR: Was this medication taken for solicited event?=No, however INJECTION SITE PAIN, MUSCLE ACHES is Solicited Events per Protocol and reported in Diary (1-7 days SAR reporting) with corresponding dates. Please verify information and update eCRF accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:23:33
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User entered empty.	System	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User entered empty.	System	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:18
User entered empty.	System	06 Oct 2020 00:34:08

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 01:26:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 01:26:29
Data point term sent to Coder	System	06 Nov 2020 01:04:08
User entered 'Ibuprofen'	Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) Susan Reed (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER,FATIGUE, INJ SITE PAIN are considered solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER,FATIGUE, INJ SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 09:47:53
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER,FATIGUE, INJ SITE PAIN are considered solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER,FATIGUE, INJ SITE PAIN did not meet the AE reporting criteria. ' answered with 'The solicited adverse reaction of fever, fatigue, injection site pain did not meet the AE reporting criteria.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	29 Dec 2020 18:31:50

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '400'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'mg (mg)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'as needed (PRN)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Oral (ORAL)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per CDM: Diary Dose 2 Day 1 "03NOV2020" has been noted for "Pain at injection site" with "Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity". So please reconcile the start date of the medication and update if medication has taken on the noted date. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 05:15:33
Query 'Per CDM: Diary Dose 2 Day 1 "03NOV2020" has been noted for "Pain at injection site" with "Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity". So please reconcile the start date of the medication and update if medication has taken on the noted date. ' answered with 'Entry corrected.' (Site from DM).	Jesse Clark (b) (4) (b) (4)	16 Feb 2021 19:47:56
User entered '3 Nov 2020' reason for change: Per Query Resolution	Jesse Clark (b) (4) (b) (4)	16 Feb 2021 19:46:41
User opened query 'Per CDM: Diary Dose 2 Day 1 "03NOV2020" has been noted for "Pain at injection site" with "Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity". So please reconcile the start date of the medication and update if medication has taken on the noted date. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:21:10
User entered '4 Nov 2020'	Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)' reason for change: New Information	(b) (4) Susan Reed (b) (4)	12 Nov 2020 19:31:26
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered '4 Nov 2020' reason for change: New Information	Susan Reed (b) (4)	12 Nov 2020 19:31:26
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	06 Nov 2020 01:03:53
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User entered empty.	System	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User entered empty.	System	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:23
User entered empty.	System	06 Nov 2020 01:03:53

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:57:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:57:34
Data point term sent to Coder	System	12 Nov 2020 19:33:08
User entered 'Excedrin - Aspirin, Acetaminophen, Caffeine'	Susan Reed (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 11:45:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'The solicited adverse reaction of headache did not meet the AE reporting criteria' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	29 Dec 2020 18:36:37

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per DM CLR: Please review recorded combination dosages and please note, this is an incorrect way of recording combination dosages. Per CCG, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please review and update to replace the commas with either a dash or a forward slash to separate the dosages. Please update or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 09:46:00
Query 'Per DM CLR: Please review recorded combination dosages and please note, this is an incorrect way of recording combination dosages. Per CCG, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please review and update to replace the commas with either a dash or a forward slash to separate the dosages. Please update or provide clarification.' answered with 'updated accordingly.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	29 Dec 2020 18:36:43
User entered '250/250/65' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	29 Dec 2020 18:33:33
User opened query 'Per DM CLR: Please review recorded combination dosages and please note, this is an incorrect way of recording combination dosages. Per CCG, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please review and update to replace the commas with either a dash or a forward slash to separate the dosages. Please update or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:44:01
User entered '250,250,65' reason for change: New Information	Susan Reed (b) (4) (b) (4)	13 Nov 2020 01:56:50
User entered '250'	Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'mg (mg)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'as needed (PRN)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Oral (ORAL)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per CDM: Diary Dose 2 Day 2 "04NOV2020" has been noted for "Headache" with "Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity". So please reconcile the start date of the medication and update if medication has taken on the noted date. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 05:14:19
Query 'Per CDM: Diary Dose 2 Day 2 "04NOV2020" has been noted for "Headache" with "Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity". So please reconcile the start date of the medication and update if medication has taken on the noted date. ' answered with 'Entry correct as entered. Ibuprofen taken 03NOV2020-04NOV2020, Excedrin taken 05NOV2020-05NOV2020.' (Site from DM).	Jesse Clark (b) (4) (b) (4)	16 Feb 2021 19:48:50
User opened query 'Per CDM: Diary Dose 2 Day 2 "04NOV2020" has been noted for "Headache" with "Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity". So please reconcile the start date of the medication and update if medication has taken on the noted date. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:18:09
User entered '5 Nov 2020'	Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '5 Nov 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User entered empty.	System	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User entered empty.	System	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:27
User entered empty.	System	12 Nov 2020 19:33:07

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 19:06:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:06:05
Data point term sent to Coder	System	24 Nov 2020 19:05:34
User entered 'EXCEDRIN - ASPIRIN, ACETAMINOPHEN, CAFFEINE'	Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Headache'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User closed query 'Per DM CLR: Please review recorded combination dosages and please note, this is an incorrect way of recording combination dosages. Per CCG, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please review and update to replace the commas with either a dash or a forward slash to separate the dosages. Please update or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 09:47:17
Query 'Per DM CLR: Please review recorded combination dosages and please note, this is an incorrect way of recording combination dosages. Per CCG, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please review and update to replace the commas with either a dash or a forward slash to separate the dosages. Please update or provide clarification. ' answered with 'updated accordingly.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	29 Dec 2020 18:37:23
User entered '250/250/65' reason for change: Data Entry Error	Mitchell Stern (b) (4) (b) (4)	29 Dec 2020 18:37:18
User opened query 'Per DM CLR: Please review recorded combination dosages and please note, this is an incorrect way of recording combination dosages. Per CCG, Dose for combination drugs should be entered using '-' (a dash) or '/' (a forward slash). Please review and update to replace the commas with either a dash or a forward slash to separate the dosages. Please update or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:49:14
User entered '250,250,65'	Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'mg (mg)'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'as needed (PRN)'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'Oral (ORAL)'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '23 Nov 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)' reason for change: New Information	(b) (4) Susan Reed (b) (4)	25 Nov 2020 22:16:10
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 22:16:10
User entered empty.	Susan Reed (b) (4)	24 Nov 2020 19:05:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User entered empty.	System	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User entered empty.	System	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:20:31
User entered empty.	System	24 Nov 2020 19:05:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;BETACAROTENE;CALCIUM CARBONATE;COLECALCIFEROL;DOCOSAHEXAENOIC ACID;FERROUS FUMARATE;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN B12 NOS;ZINC OXIDE, PRODUCTSYNONYM: PRENATAL MULTIVITAMIN + DHA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:19:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:19:53
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	01 Apr 2021 21:01:13
Data point term sent to Coder	System	01 Apr 2021 18:22:15
User entered 'Prenatal Multivitamin with 50mg of Docosahexaenoic acid'	Mitchell Stern (b) (4) (b) (4)	01 Apr 2021 18:21:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered 'General health'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered '1'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered 'tablet (TABLET)'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered 'once daily (QD)'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered '1 Jan 2021'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	01 Apr 2021 18:21:23
	(b) (4)	

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:21:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:21:23

US3682178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:05:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 18:21:23

US3682178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:05:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:03:08

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'USA-US081-2021-MRNA-1273-P301000011'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
Un-reviewed for Safety.	System	10 Mar 2021 22:47:56
User entered 'No (N)'	System	10 Mar 2021 22:47:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Yes (Y)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
Un-reviewed for Safety.	System	10 Mar 2021 22:47:56
User entered 'No (N)'	System	10 Mar 2021 22:47:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Yes (Y)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Jesse'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Clark'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'CA'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
User entered 'US'	System	09 Mar 2021 20:04:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Mar 2021 15:33:15
User entered '1'	System	09 Mar 2021 20:04:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'USA-US081-2021-MRNA-1273-P301000011'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
Un-reviewed for Safety.	System	10 Mar 2021 22:47:56
User entered 'No (N)'	System	10 Mar 2021 22:47:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Yes (Y)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
Un-reviewed for Safety.	System	10 Mar 2021 22:47:56
User entered 'No (N)'	System	10 Mar 2021 22:47:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Yes (Y)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Jesse'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Clark'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'CA'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
User entered 'US'	System	09 Mar 2021 20:04:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Mar 2021 15:33:15
User entered '1'	System	09 Mar 2021 20:04:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:05:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '09/Mar/2021 15:04'	(b) (4) System	09 Mar 2021 20:04:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:05:19

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.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 20:04:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'USA-US081-2021-MRNA-1273-P301000011'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
Un-reviewed for Safety.	System	10 Mar 2021 22:47:56
User entered 'No (N)'	System	10 Mar 2021 22:47:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Yes (Y)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'No (N)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
Un-reviewed for Safety.	System	10 Mar 2021 22:47:56
User entered 'No (N)'	System	10 Mar 2021 22:47:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Yes (Y)'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Jesse'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'Clark'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:04:03
User entered 'CA'	System	09 Mar 2021 20:03:27

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
User entered 'US'	System	09 Mar 2021 20:04:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:05:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Mar 2021 15:33:15
User entered '1'	System	09 Mar 2021 20:04:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 23:05:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
User entered '11/Mar/2021 10:33'	(b) (4) System	11 Mar 2021 15:33:15

US3682178

Folder: SAE USA-US081-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 23:05:19

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.

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:01:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:52
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 15:33:15