

US3722305 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:28:31

All time stamps listed in this document are displayed in GMT

US3722305

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Participant ID

US3722305

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

US3722305

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

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

Visit date (dd MMM yyyy)	19 AUG 2020
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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	SCRN
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US3722305

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3722305

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3722305

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3722305

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 09:52
Height (xxx.x)	65.5 in
Weight (xxx.x)	131.2 lb
BMI (xxx.x)	21.54573 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) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Date of assessment (dd MMM yyyy) 19 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 19 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

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) 09 Mar 2021 11:31:16

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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	

US3722305

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

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

Visit date (dd MMM yyyy)	19 AUG 2020
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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	VISIT1
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US3722305

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 105881

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) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Height	ND - Not Done
Weight	ND - Not Done

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

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)	19 AUG 2020
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 09:52
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

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)	19 AUG 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:58
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

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) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

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) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 10:28 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 10:28

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) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	10:09 (24 HR)
Collection date and time (derived)	19 AUG 2020 10:09

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:06	19 AUG 2020 10:06
Nasopharyngeal Swab 2	Yes	10:06	19 AUG 2020 10:06

US3722305

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

19 AUG 2020 10:58

PC Open Date & Time

19 AUG 2020 10:48

PC Close Date & Time

19 AUG 2020 13:18

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

98.1 °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

20 AUG 2020 08:09

PC Open Date & Time

19 AUG 2020 14:13

PC Close Date & Time

20 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 00:04

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

98.9 °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

21 AUG 2020 12:00

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 13:22

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 05:59

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 09:35

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

19 AUG 2020 10:59

PC Open Date & Time

19 AUG 2020 10:48

PC Close Date & Time

19 AUG 2020 13:18

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

20 AUG 2020 08:09

PC Open Date & Time

19 AUG 2020 14:13

PC Close Date & Time

20 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

21 AUG 2020 00:05

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

22 AUG 2020 13:22

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

24 AUG 2020 05:59

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

25 AUG 2020 09:35

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

25 AUG 2020 12:01

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 11:00
PC Open Date & Time	19 AUG 2020 10:48
PC Close Date & Time	19 AUG 2020 13:18

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 08:10
PC Open Date & Time	19 AUG 2020 14:13
PC Close Date & Time	20 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

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 ☒

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 00:05
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:01
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

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 ☒

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 13:22
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

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 ☒

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 06:00
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

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)

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 09:35
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3722305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments COMPLETED OOW PROTOCOL
DEVIATION TO BE REPORTED

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:31:08

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

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)	16 SEP 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 09:51
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:27
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3722305

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	16 SEP 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)	

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 10:57 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 10:57

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

US3722305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

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

Collection date (dd MMM yyyy)	16 SEP 2020
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Collection time (00:00-23:59)	10:43 (24 HR)
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Collection date and time (derived)	16 SEP 2020 10:43
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US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:39	16 SEP 2020 10:39
Nasopharyngeal Swab 2	Yes	10:39	16 SEP 2020 10:39

US3722305

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:43

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 11:26

PC Open Date & Time

16 SEP 2020 11:17

PC Close Date & Time

16 SEP 2020 13:47

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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 98.9 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 17 SEP 2020 09:51

PC Open Date & Time 16 SEP 2020 14:42

PC Close Date & Time 17 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

18 SEP 2020 09:35

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

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):

PC Time Stamp

19 SEP 2020 05:09

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 SEP 2020 20:21

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

22 SEP 2020 12:18

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

16 SEP 2020 11:25

PC Open Date & Time

16 SEP 2020 11:17

PC Close Date & Time

16 SEP 2020 13:47

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

17 SEP 2020 09:52

PC Open Date & Time

16 SEP 2020 14:42

PC Close Date & Time

17 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

18 SEP 2020 09:35

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

19 SEP 2020 05:10

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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 ☐

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

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

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

20 SEP 2020 20:21

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

22 SEP 2020 12:18

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 11:25
PC Open Date & Time	16 SEP 2020 11:17
PC Close Date & Time	16 SEP 2020 13:47

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 09:52
PC Open Date & Time	16 SEP 2020 14:42
PC Close Date & Time	17 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

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 ☒

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 09:35
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

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 ☒

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 05:10
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

Yes ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

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 ☒

PRODUCTION RELEASE (v12.003

99 of 1660

EAB) (1725)

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:21
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

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 ☒

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:00
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

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 ☒

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:18
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3722305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 17:43:44

Generated On: 12 Aug 2021 13:28:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT3

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 17:43:44

Generated On: 12 Aug 2021 13:28:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 10:56
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722305

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:43:44

Generated On: 12 Aug 2021 13:28:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3722305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 17:43:44

Generated On: 12 Aug 2021 13:28:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	11:20 (24 HR)
Collection date and time (derived)	15 OCT 2020 11:20

US3722305

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:44

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 00:47:32
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 15:19:58

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 09:32:04
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 NOV 2020 00:01:49
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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	23 NOV 2020 01:41:12
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

27 NOV 2020 00:45:56

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 00:23:31
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 06:59:16
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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	18 DEC 2020 02:39:34
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

25 DEC 2020 05:10:54

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

01 JAN 2021 01:13:18

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 00:27:38
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 00:59:51
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 11:38:54

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 13:53:21
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

05 FEB 2021 00:51:46

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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	12 FEB 2021 04:21:59
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 00:01:37
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 02:03:10
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 20:29:39

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

12 MAR 2021 17:10:45

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 MAR 2021 08:02:02
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 04:50:50

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 11:34:14
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 16:37:11
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 10:44:35

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 15:21:06
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Date and time of submission

30 APR 2021 00:38:35

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 271

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

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

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

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

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

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

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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="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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 <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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 453

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 488

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 <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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JAN 2022 00:01
Patient Cloud Close Date & Time	11 JAN 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 530

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

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

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

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

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

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

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 544

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

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

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

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

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

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

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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="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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 ☐

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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="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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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="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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 <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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3722305

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:28:31

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
Yes	No	28 FEB 2021 02:03:30

US3722305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:43:42

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 MAR 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

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 MAR 2021
Time of assessment (00:00-23:59)	10:03 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 10:03
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722305

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

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.

US3722305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 MAR 2021

Collection time (00:00-23:59)

10:05 (24 HR)

Collection date and time (derived)

1 MAR 2021 10:05

US3722305

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:31:16

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722305

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:55:27

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722305

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722305

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:28:31

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"/>

US3722305

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:28:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3722305

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

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

Visit date (dd MMM yyyy)	11 JAN 2021
--------------------------	-------------

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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US3722305

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Date of updated informed consent (dd MMM yyyy) 11 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) 11 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 _____

US3722305

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	10:46 (24 HR)
Collection date and time (derived)	11 JAN 2021 10:46

US3722305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

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

Collection date (dd MMM yyyy)	11 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	10:48
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Collection Date and Time (derived)	11 JAN 2021 10:48
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US3722305

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

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

Yes ☒

No ☐

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

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

	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 2010	
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"/>

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Name of Medication ELEVIL

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

	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 2019	
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"/>

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE, PAIN AT
INJECTION SITE

Dose per administration 325

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

	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)		20 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 AUG 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"/>

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE, PAIN AT
INJECTION SITE

Dose per administration 200

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 (4)

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 SEP 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"/>

US3722305

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:55:26

Generated On: 12 Aug 2021 13:28:31

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3722305

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:28:31

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

US3722305

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:28:31

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 ☐

Audit

US3722305 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722305

Form: Participant Creation

Generated On: 12 Aug 2021 13:28:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'US3722305'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 13:44:21

US3722305

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Sara Poff (b) (4)	19 Aug 2020 14:39:11

US3722305

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 13:44:22

US3722305

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	19 Aug 2020 14:39:11

US3722305

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'SCRN'	System	19 Aug 2020 14:39:11

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User closed query 'Per GCL Lab Recon: GCL recorded the Date of Birth as 1981; However, EDC records Date of Birth as 1985. Please reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:20:47
Query 'Per GCL Lab Recon: GCL recorded the Date of Birth as 1981; However, EDC records Date of Birth as 1985. Please reconcile. ' answered with '1985 is correct' (Site from DM).	Marlee Smith (b) (4) (b) (4)	10 Nov 2020 18:32:55
User opened query 'Per GCL Lab Recon: GCL recorded the Date of Birth as 1981; However, EDC records Date of Birth as 1985. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:02:58
Query 'Per GCL Lab Recon: GCL recorded the Date of Birth as 1985; However, EDC records Date of Birth as 1981. Please reconcile. ' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:02:42
User opened query 'Per GCL Lab Recon: GCL recorded the Date of Birth as 1985; However, EDC records Date of Birth as 1981. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:02:36
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 13:44:23

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '34'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'YEARS'	System	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered '34'	System	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Female (F)'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'I'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:28:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:39:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '19 Aug 2020'	Sara Poff (b) (4)	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'Aug 2020'	System	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered '2020'	System	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:22:28
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 15:29:51
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 15:29:47
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:41:45
User entered 'Amendment 5 (5)'	Sara Poff (b) (4) (b) (4)	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Sara Poff (b) (4)	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Sara Poff (b) (4)	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Sara Poff (b) (4)	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:40:26

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 13:44:22

US3722305

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:28:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'I'	System	19 Aug 2020 14:40:31

US3722305

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Sara Poff (b) (4)	19 Aug 2020 14:40:31

US3722305

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:28:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:44:53

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 14:46:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 14:46:26
Data point term sent to Coder	System	19 Aug 2020 14:45:57
User entered 'hypothyroidism'	Kayla Peay (b) (4)	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'un UNK 2000'	Kayla Peay (b) (4)	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Kayla Peay (b) (4)	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Kayla Peay (b) (4)	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'Jan 2000'	System	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered '2000'	System	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered empty.	System	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered empty.	System	19 Aug 2020 14:45:14

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 18:48:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 18:48:50
Data point term sent to Coder	System	17 Dec 2020 18:47:30
Coding entries removed.	Marlee Smith (b) (4)	17 Dec 2020 18:46:43
User entered 'MIGRAINE Headaches' reason for change: Data Entry Error	Marlee Smith (b) (4)	17 Dec 2020 18:46:43
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 14:46:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 14:46:26
Data point term sent to Coder	System	19 Aug 2020 14:45:57
User entered 'migraine'	Kayla Peay (b) (4)	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'un UNK 2017'	Kayla Peay (b) (4)	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Kayla Peay (b) (4)	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Kayla Peay (b) (4)	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'Jan 2017'	System	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered '2017'	System	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered empty.	System	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered empty.	System	19 Aug 2020 14:45:25

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '09:52'	Kayla Peay (b) (4)	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered '19 Aug 2020 09:52'	System	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '65.5' in	Kayla Peay (b) (4)	19 Aug 2020 14:46:20
DataPoint set to visible.	System	19 Aug 2020 14:40:31

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '131.2' lb	Kayla Peay (b) (4)	19 Aug 2020 14:46:20
DataPoint set to visible.	System	19 Aug 2020 14:40:31

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
Amendment Manager: User entered '21.54573'	System	17 Sep 2020 00:13:37
User entered '21.5'	System	19 Aug 2020 14:46:20
DataPoint set to visible.	System	19 Aug 2020 14:40:31

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'kg/m2'	System	19 Aug 2020 14:46:20
DataPoint set to visible.	System	19 Aug 2020 14:40:31

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:39
User entered '97.3' F	Kayla Peay (b) (4)	19 Aug 2020 14:46:20
	(b) (4)	

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	09 Sep 2020 12:59:39
User entered 'Oral (Oral)'	(b) (4)	
	Kayla Peay (b) (4)	19 Aug 2020 14:46:20
	(b) (4)	

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:39
User entered '64'	Kayla Peay (b) (4)	19 Aug 2020 14:46:20
	(b) (4)	

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'bpm'	System	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:39
User entered '18'	Kayla Peay (b) (4)	19 Aug 2020 14:46:20
	(b) (4)	

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'breaths/min'	System	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:39
User entered '101'	Kayla Peay (b) (4)	19 Aug 2020 14:46:20
	(b) (4)	

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'mmHg'	System	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:39
User entered '69'	Kayla Peay (b) (4)	19 Aug 2020 14:46:20
	(b) (4)	

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered 'mmHg'	System	19 Aug 2020 14:46:20

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32

US3722305

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32

US3722305

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:46:27

US3722305

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 20:25:28
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		16 Sep 2020 15:07:28
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:46:27

US3722305

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:28:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:46:42

US3722305

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:46:42

US3722305

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:46:42

US3722305

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:28:31

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:46:42

US3722305

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:46:42

US3722305

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:28:31

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Kayla Peay (b) (4)	19 Aug 2020 14:46:42

US3722305

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:46:42

US3722305

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:28:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Kayla Peay (b) (4)	19 Aug 2020 14:46:42

US3722305

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:47:48

US3722305

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:47:48

US3722305

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Urine (URINE)'	Kayla Peay (b) (4)	19 Aug 2020 14:47:48

US3722305

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Negative (NEGATIVE)'	Kayla Peay (b) (4)	19 Aug 2020 14:47:48

US3722305

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Kayla Peay (b) (4)	19 Aug 2020 14:47:48

US3722305

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:47:48

US3722305

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:47:48

US3722305

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User entered empty.	System	19 Aug 2020 14:47:48

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

[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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

[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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

[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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'I'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '0'	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:28:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:34:32
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Sara Poff (b) (4)	19 Aug 2020 14:41:04

US3722305

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Sara Poff (b) (4)	19 Aug 2020 14:41:20

US3722305

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '19 Aug 2020'	Sara Poff (b) (4)	19 Aug 2020 14:41:20

US3722305

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	19 Aug 2020 14:41:20

US3722305

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'VISIT1'	System	19 Aug 2020 14:41:20

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:15:12

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:30:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:30:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 14:15:12
User entered '105881' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:15:12

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:15:12

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:37

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:37

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:37

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:37

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'No (N)'	Sara Poff (b) (4)	19 Aug 2020 14:41:37

US3722305

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:28:31

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Per CDM: Please input yes or no in this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:35:59
Query 'Per CDM: Please input yes or no in this field.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	21 Dec 2020 20:11:23
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	21 Dec 2020 20:11:19
User opened query 'Per CDM: Please input yes or no in this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:20:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:28:34

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:28:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:46
User entered '65.5' in	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:28:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:46
User entered '131.2' lb	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:28:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:46
User entered '65.5' in	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:28:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:46
User entered '131.2' lb	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '09:52'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered '19 Aug 2020 09:52'	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '97.3' F	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '64'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'bpm'	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '18'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'breaths/min'	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '101'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'mmHg'	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '69'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'mmHg'	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:28:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:46
User entered '65.5' in	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:28:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 12:59:46
User entered '131.2' lb	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:30:44
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	19 Aug 2020 15:24:10
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 15:24:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Aug 2020 15:24:10
User entered '10:58' reason for change: Data Entry Error	Kayla Peay (b) (4)	19 Aug 2020 15:24:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 14:49:58
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered '19 Aug 2020 10:58'	System	19 Aug 2020 15:24:10
User entered empty.	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 15:24:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 15:24:10
User entered '97.2' F reason for change: Data Entry Error	Kayla Peay (b) (4)	19 Aug 2020 15:24:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 14:49:58
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 15:24:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 15:24:10
User entered '58' reason for change: Data Entry Error	Kayla Peay (b) (4)	19 Aug 2020 15:24:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 14:49:58
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'bpm'	System	19 Aug 2020 15:24:10
User entered empty.	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 15:24:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 15:24:10
User entered '18' reason for change: Data Entry Error	Kayla Peay (b) (4)	19 Aug 2020 15:24:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 14:49:58
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'breaths/min'	System	19 Aug 2020 15:24:10
User entered empty.	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 15:24:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 15:24:10
User entered '112' reason for change: Data Entry Error	Kayla Peay (b) (4)	19 Aug 2020 15:24:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 14:49:58
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'mmHg'	System	19 Aug 2020 15:24:10
User entered empty.	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 15:24:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 15:24:10
User entered '79' reason for change: Data Entry Error	Kayla Peay (b) (4)	19 Aug 2020 15:24:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 14:49:58
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:49:58
	(b) (4)	

US3722305

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'mmHg'	System	19 Aug 2020 15:24:10
User entered empty.	System	19 Aug 2020 14:49:58

US3722305

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	09 Sep 2020 12:59:53
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:50:42

US3722305

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	09 Sep 2020 12:59:53
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:50:42

US3722305

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 12:14:41
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'updated' (Site from DM).	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:49:23
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:49:17
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 02:33:01
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:50:51

US3722305

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	11 Sep 2020 19:49:17
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:50:51

US3722305

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	11 Sep 2020 19:49:17
User entered 'Urine (URINE)'	Kayla Peay (b) (4)	19 Aug 2020 14:50:51

US3722305

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty; reason for change Data Entry Error	(b) (4) Kayla Peay (b) (4)	11 Sep 2020 19:49:17
User entered 'Negative (NEGATIVE)'	(b) (4) Kayla Peay (b) (4)	19 Aug 2020 14:50:51

US3722305

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:11:54
Query 'per CDM: please select yes or no for this field' answered with 'completed' (Site from DM).	Marlee Smith (b) (4) (b) (4)	10 Nov 2020 16:38:47
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Nov 2020 16:38:42
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:35:27
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:49:17
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:50:51

US3722305

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:50:51

US3722305

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:50:51

US3722305

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered empty.	System	19 Aug 2020 14:50:51

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Sara Poff (b) (4)	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Sara Poff (b) (4)	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Sara Poff (b) (4)	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '19 Aug 2020'	Sara Poff (b) (4)	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:28'	Sara Poff (b) (4)	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered '19 Aug 2020 10:28'	System	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'ONCE'	System	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 14:42:03

US3722305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:48:17

US3722305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:48:17

US3722305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:09'	Kayla Peay (b) (4)	19 Aug 2020 14:48:17

US3722305

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered '19 Aug 2020 10:09'	System	19 Aug 2020 14:48:17

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:28:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '19 Aug 2020'	Kayla Peay (b) (4)	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:28:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:06'	Kayla Peay (b) (4)	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered '19 Aug 2020 10:06'	System	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:28:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:06'	Kayla Peay (b) (4)	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered '19 Aug 2020 10:06'	System	19 Aug 2020 14:48:34

US3722305

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:48:39

US3722305

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered '1'	System	19 Aug 2020 14:48:39

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:58:26', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a4e76337-4c49-411d-bea3-586bd7804703'	System	19 Aug 2020 14:58:57
User entered 'Yes (Y)'	System	19 Aug 2020 14:58:57

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:58:47', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a4e76337-4c49-411d-bea3-586bd7804703' User entered '97.2'	System	19 Aug 2020 14:58:57
	System	19 Aug 2020 14:58:57

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:58:51', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a4e76337-4c49-411d-bea3-586bd7804703'	System	19 Aug 2020 14:58:57
User entered 'No (N)'	System	19 Aug 2020 14:58:57

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:58:54', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a4e76337-4c49-411d-bea3-586bd7804703'	System	19 Aug 2020 14:58:57
User entered '19 Aug 2020 10:58'	System	19 Aug 2020 14:58:57

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 10:48'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 13:18'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:02', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd456d10c-a4a1-4679-9b54-a8b713549b20'	System	20 Aug 2020 12:09:19
User entered 'Yes (Y)'	System	20 Aug 2020 12:09:19

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:06', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd456d10c-a4a1-4679-9b54-a8b713549b20' User entered '98.1'	System	20 Aug 2020 12:09:19
	System	20 Aug 2020 12:09:19

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd456d10c-a4a1-4679-9b54-a8b713549b20'	System	20 Aug 2020 12:09:19
User entered 'No (N)'	System	20 Aug 2020 12:09:19

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:16', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd456d10c-a4a1-4679-9b54-a8b713549b20'	System	20 Aug 2020 12:09:19
User entered '20 Aug 2020 08:09'	System	20 Aug 2020 12:09:19

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 14:13'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 2'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:04:24', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '51c9e6bb-be23-45a2-8c5b-04382b948404' User entered 'Yes (Y)'	System	21 Aug 2020 04:04:54
	System	21 Aug 2020 04:04:54

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:04:29', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '51c9e6bb-be23-45a2-8c5b-04382b948404' User entered '98.1'	System	21 Aug 2020 04:04:54
	System	21 Aug 2020 04:04:54

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:04:35', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '51c9e6bb-be23-45a2-8c5b-04382b948404'	System	21 Aug 2020 04:04:54
User entered 'Yes (Y)'	System	21 Aug 2020 04:04:54

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
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 'confirmed' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 22:35:37
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).	Amy Ford (b) (4)	20 Oct 2020 23:16:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:04:44', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '51c9e6bb-be23-45a2-8c5b-04382b948404'	(b) (4)	
User entered '1'	System	21 Aug 2020 04:04:54

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:04:44', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '51c9e6bb-be23-45a2-8c5b-04382b948404' User entered '0'	System	21 Aug 2020 04:04:54
	System	21 Aug 2020 04:04:54

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:04:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '51c9e6bb-be23-45a2-8c5b-04382b948404' User entered '21 Aug 2020 00:04'	System	21 Aug 2020 04:04:54
	System	21 Aug 2020 04:04:54

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 3'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:00:14', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9cae358a-a7f1-4837-8c7d-0e1c6f6e7087' User entered 'Yes (Y)'	System	21 Aug 2020 16:00:39
	System	21 Aug 2020 16:00:39

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:00:17', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9cae358a-a7f1-4837-8c7d-0e1c6f6e7087' User entered '98.9'	System	21 Aug 2020 16:00:39
	System	21 Aug 2020 16:00:39

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:00:30', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9cae358a-a7f1-4837-8c7d-0e1c6f6e7087'	System	21 Aug 2020 16:00:39
User entered 'No (N)'	System	21 Aug 2020 16:00:39

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:00:34', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9cae358a-a7f1-4837-8c7d-0e1c6f6e7087'	System	21 Aug 2020 16:00:39
User entered '21 Aug 2020 12:00'	System	21 Aug 2020 16:00:39

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 4'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:02', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1d105c2a-32a4-4756-bc9e-e89d9604bd63' User entered 'Yes (Y)'	System	22 Aug 2020 17:22:14
	System	22 Aug 2020 17:22:14

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:06', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1d105c2a-32a4-4756-bc9e-e89d9604bd63' User entered '99.2'	System	22 Aug 2020 17:22:14
	System	22 Aug 2020 17:22:14

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:10', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1d105c2a-32a4-4756-bc9e-e89d9604bd63'	System	22 Aug 2020 17:22:14
User entered 'No (N)'	System	22 Aug 2020 17:22:14

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1d105c2a-32a4-4756-bc9e-e89d9604bd63'	System	22 Aug 2020 17:22:14
User entered '22 Aug 2020 13:22'	System	22 Aug 2020 17:22:14

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 5'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:25', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'fb5fb702-675a-45e3-9080-a1cae4249b2e' User entered 'Yes (Y)'	System	24 Aug 2020 09:59:52
	System	24 Aug 2020 09:59:52

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:30', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'fb5fb702-675a-45e3-9080-a1cae4249b2e' User entered '97.6'	System	24 Aug 2020 09:59:52
	System	24 Aug 2020 09:59:52

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:34', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'fb5fb702-675a-45e3-9080-a1cae4249b2e' User entered 'No (N)'	System	24 Aug 2020 09:59:52
	System	24 Aug 2020 09:59:52

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:36', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'fb5fb702-675a-45e3-9080-a1cae4249b2e' User entered '24 Aug 2020 05:59'	System	24 Aug 2020 09:59:52
	System	24 Aug 2020 09:59:52

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 6'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd39dcfa4-62df-43a7-bfce-e4ffd046d6ea' User entered 'Yes (Y)'	System	25 Aug 2020 13:35:24
	System	25 Aug 2020 13:35:24

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:15', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd39dcfa4-62df-43a7-bfce-e4ffd046d6ea' User entered '99.2'	System	25 Aug 2020 13:35:24
	System	25 Aug 2020 13:35:24

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:18', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd39dcfa4-62df-43a7-bfce-e4ffd046d6ea'	System	25 Aug 2020 13:35:24
User entered 'No (N)'	System	25 Aug 2020 13:35:24

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:21', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd39dcfa4-62df-43a7-bfce-e4ffd046d6ea' User entered '25 Aug 2020 09:35'	System	25 Aug 2020 13:35:24
	System	25 Aug 2020 13:35:24

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 7'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:00:49', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5a5f5887-2870-4243-baee-b72b8df46bf5' User entered 'Yes (Y)'	System	25 Aug 2020 16:01:09
	System	25 Aug 2020 16:01:09

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:00:53', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5a5f5887-2870-4243-baee-b72b8df46bf5' User entered '98.9'	System	25 Aug 2020 16:01:09
	System	25 Aug 2020 16:01:09

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:00:55', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5a5f5887-2870-4243-baee-b72b8df46bf5'	System	25 Aug 2020 16:01:09
User entered 'No (N)'	System	25 Aug 2020 16:01:09

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:00:57', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5a5f5887-2870-4243-baee-b72b8df46bf5'	System	25 Aug 2020 16:01:09
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 16:01:09

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:18', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a042d356-f33b-4f16-a739-34c873eb30e6'	System	19 Aug 2020 14:59:37
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 14:59:37

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:25', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a042d356-f33b-4f16-a739-34c873eb30e6' User entered 'No (N)'	System	19 Aug 2020 14:59:37
	System	19 Aug 2020 14:59:37

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:27', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a042d356-f33b-4f16-a739-34c873eb30e6' User entered 'No (N)'	System	19 Aug 2020 14:59:37
	System	19 Aug 2020 14:59:37

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:32', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a042d356-f33b-4f16-a739-34c873eb30e6'	System	19 Aug 2020 14:59:37
User entered 'None (1)'	System	19 Aug 2020 14:59:37

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:34', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a042d356-f33b-4f16-a739-34c873eb30e6' User entered '19 Aug 2020 10:59'	System	19 Aug 2020 14:59:37
	System	19 Aug 2020 14:59:37

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 10:48'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 13:18'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:28', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '49e74467-67fb-4d4a-9a42-8776f145b9bf' User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 12:09:51
	System	20 Aug 2020 12:09:51

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:30', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '49e74467-67fb-4d4a-9a42-8776f145b9bf' User entered 'No (N)'	System	20 Aug 2020 12:09:51
	System	20 Aug 2020 12:09:51

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:37', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '49e74467-67fb-4d4a-9a42-8776f145b9bf' User entered 'No (N)'	System	20 Aug 2020 12:09:51
	System	20 Aug 2020 12:09:51

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:45', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '49e74467-67fb-4d4a-9a42-8776f145b9bf' User entered 'None (1)'	System	20 Aug 2020 12:09:51
	System	20 Aug 2020 12:09:51

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:47', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '49e74467-67fb-4d4a-9a42-8776f145b9bf' User entered '20 Aug 2020 08:09'	System	20 Aug 2020 12:09:51
	System	20 Aug 2020 12:09:51

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 14:13'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 2'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:04:58', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9f6f693e-1645-4e12-ac42-44b4f95fba3e'	System	21 Aug 2020 04:05:12
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	21 Aug 2020 04:05:12

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9f6f693e-1645-4e12-ac42-44b4f95fba3e' User entered 'No (N)'	System	21 Aug 2020 04:05:12
	System	21 Aug 2020 04:05:12

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:03', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9f6f693e-1645-4e12-ac42-44b4f95fba3e' User entered 'No (N)'	System	21 Aug 2020 04:05:12
	System	21 Aug 2020 04:05:12

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:08', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9f6f693e-1645-4e12-ac42-44b4f95fba3e' User entered 'None (1)'	System	21 Aug 2020 04:05:12
	System	21 Aug 2020 04:05:12

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:11', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9f6f693e-1645-4e12-ac42-44b4f95fba3e' User entered '21 Aug 2020 00:05'	System	21 Aug 2020 04:05:12
	System	21 Aug 2020 04:05:12

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 3'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:00:51', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc8db48e-ca7e-4c32-9064-b13d78c86f98'	System	21 Aug 2020 16:01:15
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 16:01:15

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:00:57', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc8db48e-ca7e-4c32-9064-b13d78c86f98' User entered 'No (N)'	System	21 Aug 2020 16:01:15
	System	21 Aug 2020 16:01:15

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:01', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc8db48e-ca7e-4c32-9064-b13d78c86f98'	System	21 Aug 2020 16:01:15
User entered 'No (N)'	System	21 Aug 2020 16:01:15

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:05', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc8db48e-ca7e-4c32-9064-b13d78c86f98'	System	21 Aug 2020 16:01:15
User entered 'None (1)'	System	21 Aug 2020 16:01:15

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:08', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc8db48e-ca7e-4c32-9064-b13d78c86f98'	System	21 Aug 2020 16:01:15
User entered '21 Aug 2020 12:01'	System	21 Aug 2020 16:01:15

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 4'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:17', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '80b38c6d-3be3-4c99-ac51-008186e2e368'	System	22 Aug 2020 17:22:27
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 17:22:27

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:19', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '80b38c6d-3be3-4c99-ac51-008186e2e368' User entered 'No (N)'	System	22 Aug 2020 17:22:27
	System	22 Aug 2020 17:22:27

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:21', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '80b38c6d-3be3-4c99-ac51-008186e2e368'	System	22 Aug 2020 17:22:27
User entered 'No (N)'	System	22 Aug 2020 17:22:27

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:23', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '80b38c6d-3be3-4c99-ac51-008186e2e368'	System	22 Aug 2020 17:22:27
User entered 'None (1)'	System	22 Aug 2020 17:22:27

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:26', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '80b38c6d-3be3-4c99-ac51-008186e2e368' User entered '22 Aug 2020 13:22'	System	22 Aug 2020 17:22:27
	System	22 Aug 2020 17:22:27

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 5'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:41', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9be0a6bb-79cc-425a-8529-0d18896425b6' User entered 'None (1)'	System	24 Aug 2020 09:59:55
	System	24 Aug 2020 09:59:55

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:43', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9be0a6bb-79cc-425a-8529-0d18896425b6' User entered 'No (N)'	System	24 Aug 2020 09:59:55
	System	24 Aug 2020 09:59:55

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:46', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9be0a6bb-79cc-425a-8529-0d18896425b6' User entered 'No (N)'	System	24 Aug 2020 09:59:55
	System	24 Aug 2020 09:59:55

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:48', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9be0a6bb-79cc-425a-8529-0d18896425b6' User entered 'None (1)'	System	24 Aug 2020 09:59:55
	System	24 Aug 2020 09:59:55

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9be0a6bb-79cc-425a-8529-0d18896425b6' User entered '24 Aug 2020 05:59'	System	24 Aug 2020 09:59:55
	System	24 Aug 2020 09:59:55

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 6'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:24', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '00c78a94-3dee-4103-8b4b-17c3889631d3'	System	25 Aug 2020 13:35:36
User entered 'None (1)'	System	25 Aug 2020 13:35:36

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:26', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '00c78a94-3dee-4103-8b4b-17c3889631d3' User entered 'No (N)'	System	25 Aug 2020 13:35:36
	System	25 Aug 2020 13:35:36

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:28', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '00c78a94-3dee-4103-8b4b-17c3889631d3' User entered 'No (N)'	System	25 Aug 2020 13:35:36
	System	25 Aug 2020 13:35:36

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:30', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '00c78a94-3dee-4103-8b4b-17c3889631d3'	System	25 Aug 2020 13:35:36
User entered 'None (1)'	System	25 Aug 2020 13:35:36

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:31', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '00c78a94-3dee-4103-8b4b-17c3889631d3' User entered '25 Aug 2020 09:35'	System	25 Aug 2020 13:35:36
	System	25 Aug 2020 13:35:36

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 7'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '66349e7f-5f8c-4350-a733-c4825fe40764' User entered 'None (1)'	System	25 Aug 2020 16:01:24
	System	25 Aug 2020 16:01:24

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:02', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '66349e7f-5f8c-4350-a733-c4825fe40764' User entered 'No (N)'	System	25 Aug 2020 16:01:24
	System	25 Aug 2020 16:01:24

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:04', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '66349e7f-5f8c-4350-a733-c4825fe40764' User entered 'No (N)'	System	25 Aug 2020 16:01:24
	System	25 Aug 2020 16:01:24

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:06', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '66349e7f-5f8c-4350-a733-c4825fe40764' User entered 'None (1)'	System	25 Aug 2020 16:01:24
	System	25 Aug 2020 16:01:24

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:08', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '66349e7f-5f8c-4350-a733-c4825fe40764' User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:01:24
	System	25 Aug 2020 16:01:24

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:40', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '86e83eae-cd45-4516-a088-30541278775f' User entered 'None (0)'	System	19 Aug 2020 15:00:05
	System	19 Aug 2020 15:00:05

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:43', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '86e83eae-cd45-4516-a088-30541278775f' User entered 'None (0)'	System	19 Aug 2020 15:00:05
	System	19 Aug 2020 15:00:05

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:48', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '86e83eae-cd45-4516-a088-30541278775f' User entered 'None (0)'	System	19 Aug 2020 15:00:05
	System	19 Aug 2020 15:00:05

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '86e83eae-cd45-4516-a088-30541278775f' User entered 'None (0)'	System	19 Aug 2020 15:00:05
	System	19 Aug 2020 15:00:05

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:53', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '86e83eae-cd45-4516-a088-30541278775f' User entered 'None (0)'	System	19 Aug 2020 15:00:05
	System	19 Aug 2020 15:00:05

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:55', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '86e83eae-cd45-4516-a088-30541278775f' User entered 'None (0)'	System	19 Aug 2020 15:00:05
	System	19 Aug 2020 15:00:05

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T10:59:59', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '86e83eae-cd45-4516-a088-30541278775f' User entered 'No (N)'	System	19 Aug 2020 15:00:05
	System	19 Aug 2020 15:00:05

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-19T11:00:02', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '86e83eae-cd45-4516-a088-30541278775f' User entered '19 Aug 2020 11:00'	System	19 Aug 2020 15:00:05
	System	19 Aug 2020 15:00:05

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 10:48'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 13:18'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:09:57', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '22df5a60-c0bd-4c81-8334-31ae60431e45'	System	20 Aug 2020 12:10:28
User entered 'No interference with activity (1)'	System	20 Aug 2020 12:10:28

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:10:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '22df5a60-c0bd-4c81-8334-31ae60431e45' User entered 'None (0)'	System	20 Aug 2020 12:10:28
	System	20 Aug 2020 12:10:28

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:10:03', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '22df5a60-c0bd-4c81-8334-31ae60431e45' User entered 'None (0)'	System	20 Aug 2020 12:10:28
	System	20 Aug 2020 12:10:28

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:10:05', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '22df5a60-c0bd-4c81-8334-31ae60431e45' User entered 'None (0)'	System	20 Aug 2020 12:10:28
	System	20 Aug 2020 12:10:28

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:10:10', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '22df5a60-c0bd-4c81-8334-31ae60431e45'	System	20 Aug 2020 12:10:28
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Aug 2020 12:10:28

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:10:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '22df5a60-c0bd-4c81-8334-31ae60431e45' User entered 'None (0)'	System	20 Aug 2020 12:10:28
	System	20 Aug 2020 12:10:28

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:10:16', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '22df5a60-c0bd-4c81-8334-31ae60431e45'	System	20 Aug 2020 12:10:28
User entered 'No (N)'	System	20 Aug 2020 12:10:28

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-20T08:10:22', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '22df5a60-c0bd-4c81-8334-31ae60431e45' User entered '20 Aug 2020 08:10'	System	20 Aug 2020 12:10:28
	System	20 Aug 2020 12:10:28

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Aug 2020 14:13'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 2'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:17', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3eb17e59-32ca-49f6-8853-0dc3f94cd40c'	System	21 Aug 2020 04:05:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	21 Aug 2020 04:05:49

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:21', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3eb17e59-32ca-49f6-8853-0dc3f94cd40c'	System	21 Aug 2020 04:05:49
User entered 'Some interference with activity (2)'	System	21 Aug 2020 04:05:49

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:26', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3eb17e59-32ca-49f6-8853-0dc3f94cd40c' User entered 'None (0)'	System	21 Aug 2020 04:05:49
	System	21 Aug 2020 04:05:49

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:29', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3eb17e59-32ca-49f6-8853-0dc3f94cd40c' User entered 'None (0)'	System	21 Aug 2020 04:05:49
	System	21 Aug 2020 04:05:49

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:38', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3eb17e59-32ca-49f6-8853-0dc3f94cd40c'	System	21 Aug 2020 04:05:49
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Aug 2020 04:05:49

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:41', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3eb17e59-32ca-49f6-8853-0dc3f94cd40c' User entered 'None (0)'	System	21 Aug 2020 04:05:49
	System	21 Aug 2020 04:05:49

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:44', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3eb17e59-32ca-49f6-8853-0dc3f94cd40c' User entered 'No (N)'	System	21 Aug 2020 04:05:49
	System	21 Aug 2020 04:05:49

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T00:05:47', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3eb17e59-32ca-49f6-8853-0dc3f94cd40c' User entered '21 Aug 2020 00:05'	System	21 Aug 2020 04:05:49
	System	21 Aug 2020 04:05:49

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 3'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:15', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '4f750307-a06f-4bcd-8e22-8cddd4e88353'	System	21 Aug 2020 16:01:55
User entered 'No interference with activity (1)'	System	21 Aug 2020 16:01:55

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:20', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '4f750307-a06f-4bcd-8e22-8cddd4e88353'	System	21 Aug 2020 16:01:55
User entered 'Some interference with activity (2)'	System	21 Aug 2020 16:01:55

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:32', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '4f750307-a06f-4bcd-8e22-8cddd4e88353'	System	21 Aug 2020 16:01:55
User entered 'No interference with activity (1)'	System	21 Aug 2020 16:01:55

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:35', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '4f750307-a06f-4bcd-8e22-8cddd4e88353' User entered 'None (0)'	System	21 Aug 2020 16:01:55
	System	21 Aug 2020 16:01:55

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:40', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '4f750307-a06f-4bcd-8e22-8cddd4e88353' User entered 'None (0)'	System	21 Aug 2020 16:01:55
	System	21 Aug 2020 16:01:55

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:45', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '4f750307-a06f-4bcd-8e22-8cddd4e88353' User entered 'None (0)'	System	21 Aug 2020 16:01:55
	System	21 Aug 2020 16:01:55

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '4f750307-a06f-4bcd-8e22-8cddd4e88353'	System	21 Aug 2020 16:01:55
User entered 'No (N)'	System	21 Aug 2020 16:01:55

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-21T12:01:53', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '4f750307-a06f-4bcd-8e22-8cddd4e88353' User entered '21 Aug 2020 12:01'	System	21 Aug 2020 16:01:55
	System	21 Aug 2020 16:01:55

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 4'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:30', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bd028878-c9b5-462f-b1f3-04e8896f608d' User entered 'None (0)'	System	22 Aug 2020 17:22:52
	System	22 Aug 2020 17:22:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:33', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bd028878-c9b5-462f-b1f3-04e8896f608d'	System	22 Aug 2020 17:22:52
User entered 'No interference with activity (1)'	System	22 Aug 2020 17:22:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:36', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bd028878-c9b5-462f-b1f3-04e8896f608d' User entered 'None (0)'	System	22 Aug 2020 17:22:52
	System	22 Aug 2020 17:22:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:38', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bd028878-c9b5-462f-b1f3-04e8896f608d' User entered 'None (0)'	System	22 Aug 2020 17:22:52
	System	22 Aug 2020 17:22:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:40', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bd028878-c9b5-462f-b1f3-04e8896f608d' User entered 'None (0)'	System	22 Aug 2020 17:22:52
	System	22 Aug 2020 17:22:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:42', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bd028878-c9b5-462f-b1f3-04e8896f608d' User entered 'None (0)'	System	22 Aug 2020 17:22:52
	System	22 Aug 2020 17:22:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:46', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bd028878-c9b5-462f-b1f3-04e8896f608d' User entered 'No (N)'	System	22 Aug 2020 17:22:52
	System	22 Aug 2020 17:22:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-22T13:22:49', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bd028878-c9b5-462f-b1f3-04e8896f608d' User entered '22 Aug 2020 13:22'	System	22 Aug 2020 17:22:52
	System	22 Aug 2020 17:22:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 5'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T05:59:56', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '8d57f823-2e0f-4b73-a4c9-50ac945ba9ce'	System	24 Aug 2020 10:00:22
User entered 'No interference with activity (1)'	System	24 Aug 2020 10:00:22

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T06:00:02', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '8d57f823-2e0f-4b73-a4c9-50ac945ba9ce'	System	24 Aug 2020 10:00:22
User entered 'No interference with activity (1)'	System	24 Aug 2020 10:00:22

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T06:00:05', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '8d57f823-2e0f-4b73-a4c9-50ac945ba9ce' User entered 'None (0)'	System	24 Aug 2020 10:00:22
	System	24 Aug 2020 10:00:22

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T06:00:07', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '8d57f823-2e0f-4b73-a4c9-50ac945ba9ce' User entered 'None (0)'	System	24 Aug 2020 10:00:22
	System	24 Aug 2020 10:00:22

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T06:00:10', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '8d57f823-2e0f-4b73-a4c9-50ac945ba9ce' User entered 'None (0)'	System	24 Aug 2020 10:00:22
	System	24 Aug 2020 10:00:22

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T06:00:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '8d57f823-2e0f-4b73-a4c9-50ac945ba9ce' User entered 'None (0)'	System	24 Aug 2020 10:00:22
	System	24 Aug 2020 10:00:22

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T06:00:15', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '8d57f823-2e0f-4b73-a4c9-50ac945ba9ce'	System	24 Aug 2020 10:00:22
User entered 'No (N)'	System	24 Aug 2020 10:00:22

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-24T06:00:18', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '8d57f823-2e0f-4b73-a4c9-50ac945ba9ce'	System	24 Aug 2020 10:00:22
User entered '24 Aug 2020 06:00'	System	24 Aug 2020 10:00:22

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 6'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:35', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'f53bad9e-8a29-45d5-ac4b-9e3ee83c4fca' User entered 'None (0)'	System	25 Aug 2020 13:35:52
	System	25 Aug 2020 13:35:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:36', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'f53bad9e-8a29-45d5-ac4b-9e3ee83c4fca' User entered 'None (0)'	System	25 Aug 2020 13:35:52
	System	25 Aug 2020 13:35:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:37', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'f53bad9e-8a29-45d5-ac4b-9e3ee83c4fca' User entered 'None (0)'	System	25 Aug 2020 13:35:52
	System	25 Aug 2020 13:35:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:39', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'f53bad9e-8a29-45d5-ac4b-9e3ee83c4fca' User entered 'None (0)'	System	25 Aug 2020 13:35:52
	System	25 Aug 2020 13:35:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:40', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'f53bad9e-8a29-45d5-ac4b-9e3ee83c4fca' User entered 'None (0)'	System	25 Aug 2020 13:35:52
	System	25 Aug 2020 13:35:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:42', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'f53bad9e-8a29-45d5-ac4b-9e3ee83c4fca' User entered 'None (0)'	System	25 Aug 2020 13:35:52
	System	25 Aug 2020 13:35:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:44', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'f53bad9e-8a29-45d5-ac4b-9e3ee83c4fca' User entered 'No (N)'	System	25 Aug 2020 13:35:52
	System	25 Aug 2020 13:35:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T09:35:46', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'f53bad9e-8a29-45d5-ac4b-9e3ee83c4fca' User entered '25 Aug 2020 09:35'	System	25 Aug 2020 13:35:52
	System	25 Aug 2020 13:35:52

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 7'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:11', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3f520444-7676-4050-aa00-b7a8bfd47ec6' User entered 'None (0)'	System	25 Aug 2020 16:01:39
	System	25 Aug 2020 16:01:39

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:13', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3f520444-7676-4050-aa00-b7a8bfd47ec6' User entered 'None (0)'	System	25 Aug 2020 16:01:39
	System	25 Aug 2020 16:01:39

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:14', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3f520444-7676-4050-aa00-b7a8bfd47ec6' User entered 'None (0)'	System	25 Aug 2020 16:01:39
	System	25 Aug 2020 16:01:39

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:15', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3f520444-7676-4050-aa00-b7a8bfd47ec6' User entered 'None (0)'	System	25 Aug 2020 16:01:39
	System	25 Aug 2020 16:01:39

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:16', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3f520444-7676-4050-aa00-b7a8bfd47ec6' User entered 'None (0)'	System	25 Aug 2020 16:01:39
	System	25 Aug 2020 16:01:39

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:18', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3f520444-7676-4050-aa00-b7a8bfd47ec6' User entered 'None (0)'	System	25 Aug 2020 16:01:39
	System	25 Aug 2020 16:01:39

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:20', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3f520444-7676-4050-aa00-b7a8bfd47ec6' User entered 'No (N)'	System	25 Aug 2020 16:01:39
	System	25 Aug 2020 16:01:39

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-08-25T12:01:22', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3f520444-7676-4050-aa00-b7a8bfd47ec6' User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:01:39
	System	25 Aug 2020 16:01:39

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 14:42:03

US3722305

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Amy Ford (b) (4)	31 Aug 2020 20:21:01

US3722305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 10:44:56
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'COMPLETED OOW PROTOCOL DEVIATION TO BE REPORTED' (Site from System).	Amy Ford (b) (4) (b) (4)	31 Aug 2020 20:21:06
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	31 Aug 2020 20:21:01
User entered '31 Aug 2020'	Amy Ford (b) (4) (b) (4)	31 Aug 2020 20:21:01

US3722305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	31 Aug 2020 20:21:01

US3722305

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'COMPLETED OOW PROTOCOL DEVIATION TO BE REPORTED'	Amy Ford (b) (4)	31 Aug 2020 20:21:01

US3722305

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Amy Ford (b) (4)	31 Aug 2020 20:21:18

US3722305

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered 'I'	System	31 Aug 2020 20:21:18

US3722305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Kayla Peay (b) (4)	03 Sep 2020 18:29:11

US3722305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '2 Sep 2020'	Kayla Peay (b) (4)	03 Sep 2020 18:29:11

US3722305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	03 Sep 2020 18:29:11

US3722305

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Kayla Peay (b) (4)	03 Sep 2020 18:29:11

US3722305

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:08
User entered 'Yes (Y)'	Kayla Peay (b) (4)	03 Sep 2020 18:29:15

US3722305

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:42:59
User entered '1'	System	03 Sep 2020 18:29:15

US3722305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	10 Sep 2020 19:17:17

US3722305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '9 Sep 2020'	Kayla Peay (b) (4)	10 Sep 2020 19:17:17

US3722305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	10 Sep 2020 19:17:17

US3722305

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	10 Sep 2020 19:17:17

US3722305

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	10 Sep 2020 19:17:20

US3722305

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'I'	System	10 Sep 2020 19:17:20

US3722305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Sara Poff (b) (4)	16 Sep 2020 15:07:28

US3722305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16 Sep 2020'	Sara Poff (b) (4)	16 Sep 2020 15:07:28

US3722305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	16 Sep 2020 15:07:28

US3722305

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'VISIT2'	System	16 Sep 2020 15:07:28

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16 Sep 2020'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '09:51'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '16 Sep 2020 09:51'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '98' F	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '57'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'bpm'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '17'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'breaths/min'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '94'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'mmHg'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:22:41
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 'abnormal NCS' (Site from System).	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 15:44:46
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:13:37
User entered '58'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'mmHg'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16 Sep 2020'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '11:27'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '16 Sep 2020 11:27'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '98.2' F	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '55'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'bpm'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '14'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'breaths/min'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '90'	Kayla Peay (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'mmHg'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:22:44
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 'abnormal NCS' (Site from System).	Kayla Peay (b) (4) (b) (4)	25 Sep 2020 15:45:02
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:13:37
User entered '59'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'mmHg'	System	16 Sep 2020 17:48:49

US3722305

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 17:48:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16 Sep 2020'	Kayla Peay (b) (4)	16 Sep 2020 17:48:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 17:49:06

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16 Sep 2020'	Kayla Peay (b) (4)	16 Sep 2020 17:49:06

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Urine (URINE)'	Kayla Peay (b) (4)	16 Sep 2020 17:49:06

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Negative (NEGATIVE)'	Kayla Peay (b) (4)	16 Sep 2020 17:49:06

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'No (N)'	Kayla Peay (b) (4)	16 Sep 2020 17:49:06

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	16 Sep 2020 17:49:06

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	16 Sep 2020 17:49:06

US3722305

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered empty.	System	16 Sep 2020 17:49:06

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Sara Poff (b) (4)	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Sara Poff (b) (4)	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Sara Poff (b) (4)	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16 Sep 2020'	Sara Poff (b) (4)	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:57'	Sara Poff (b) (4)	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '16 Sep 2020 10:57'	System	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'ONCE'	System	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:28:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 15:07:59

US3722305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 17:49:16

US3722305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16 Sep 2020'	Kayla Peay (b) (4)	16 Sep 2020 17:49:16

US3722305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:43'	Kayla Peay (b) (4)	16 Sep 2020 17:49:16

US3722305

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '16 Sep 2020 10:43'	System	16 Sep 2020 17:49:16

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:28:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16 Sep 2020'	Kayla Peay (b) (4)	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:28:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:39'	Kayla Peay (b) (4)	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '16 Sep 2020 10:39'	System	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:28:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:39'	Kayla Peay (b) (4)	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:28:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '16 Sep 2020 10:39'	System	16 Sep 2020 17:49:27

US3722305

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Sara Poff (b) (4)	16 Sep 2020 15:08:08

US3722305

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '1'	System	16 Sep 2020 15:08:08

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:41', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '82e1c366-ee4d-4085-aa80-709506f0859f' User entered 'Yes (Y)'	System	16 Sep 2020 15:26:28
	System	16 Sep 2020 15:26:28

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:26:19', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '82e1c366-ee4d-4085-aa80-709506f0859f' User entered '98.2'	System	16 Sep 2020 15:26:28
	System	16 Sep 2020 15:26:28

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:26:23', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '82e1c366-ee4d-4085-aa80-709506f0859f' User entered 'No (N)'	System	16 Sep 2020 15:26:28
	System	16 Sep 2020 15:26:28

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:26:25', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '82e1c366-ee4d-4085-aa80-709506f0859f' User entered '16 Sep 2020 11:26'	System	16 Sep 2020 15:26:28
	System	16 Sep 2020 15:26:28

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 11:17'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 13:47'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:51:22', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce8ef867-1a29-4e69-8f2c-80b682746354'	System	17 Sep 2020 13:51:39
User entered 'Yes (Y)'	System	17 Sep 2020 13:51:39

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:51:25', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce8ef867-1a29-4e69-8f2c-80b682746354' User entered '98.9'	System	17 Sep 2020 13:51:39
	System	17 Sep 2020 13:51:39

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:51:30', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce8ef867-1a29-4e69-8f2c-80b682746354'	System	17 Sep 2020 13:51:39
User entered 'Yes (Y)'	System	17 Sep 2020 13:51:39

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
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 'confirmed' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 04:37:44
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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:51:35', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce8ef867-1a29-4e69-8f2c-80b682746354' User entered '1'	Marlee Smith (b) (4)	10 Nov 2020 19:23:13
	(b) (4)	
	System	17 Sep 2020 13:51:39
	System	17 Sep 2020 13:51:39
	System	17 Sep 2020 13:51:39

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:51:35', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce8ef867-1a29-4e69-8f2c-80b682746354' User entered '0'	System	17 Sep 2020 13:51:39
	System	17 Sep 2020 13:51:39

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:51:37', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce8ef867-1a29-4e69-8f2c-80b682746354' User entered '17 Sep 2020 09:51'	System	17 Sep 2020 13:51:39
	System	17 Sep 2020 13:51:39

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 14:42'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 2'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:24', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '2247d085-037f-4db9-a40a-350fd992c31a' User entered 'Yes (Y)'	System	18 Sep 2020 13:35:38
	System	18 Sep 2020 13:35:38

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:27', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '2247d085-037f-4db9-a40a-350fd992c31a' User entered '98.4'	System	18 Sep 2020 13:35:38
	System	18 Sep 2020 13:35:38

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:30', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '2247d085-037f-4db9-a40a-350fd992c31a' User entered 'No (N)'	System	18 Sep 2020 13:35:38
	System	18 Sep 2020 13:35:38

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:32', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '2247d085-037f-4db9-a40a-350fd992c31a' User entered '18 Sep 2020 09:35'	System	18 Sep 2020 13:35:38
	System	18 Sep 2020 13:35:38

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 3'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:09:41', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6cee6810-ee07-4845-93c4-31796f4fa13b' User entered 'Yes (Y)'	System	19 Sep 2020 09:09:57
	System	19 Sep 2020 09:09:57

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:09:46', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6cee6810-ee07-4845-93c4-31796f4fa13b' User entered '98.2'	System	19 Sep 2020 09:09:57
	System	19 Sep 2020 09:09:57

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:09:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6cee6810-ee07-4845-93c4-31796f4fa13b'	System	19 Sep 2020 09:09:57
User entered 'No (N)'	System	19 Sep 2020 09:09:57

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:09:53', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6cee6810-ee07-4845-93c4-31796f4fa13b' User entered '19 Sep 2020 05:09'	System	19 Sep 2020 09:09:57
	System	19 Sep 2020 09:09:57

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 4'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 5'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:01', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e8f970a0-7a37-4a74-985a-fc9f5bf4d072'	System	21 Sep 2020 00:21:17
User entered 'Yes (Y)'	System	21 Sep 2020 00:21:17

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:03', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e8f970a0-7a37-4a74-985a-fc9f5bf4d072' User entered '98.1'	System	21 Sep 2020 00:21:17
	System	21 Sep 2020 00:21:17

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:08', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e8f970a0-7a37-4a74-985a-fc9f5bf4d072'	System	21 Sep 2020 00:21:17
User entered 'Yes (Y)'	System	21 Sep 2020 00:21:17

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
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 'confirmed' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 04:37:56
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).	Marlee Smith (b) (4)	10 Nov 2020 19:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e8f970a0-7a37-4a74-985a-fc9f5bf4d072'	(b) (4)	
User entered '1'	System	21 Sep 2020 00:21:17
	System	21 Sep 2020 00:21:17
	System	21 Sep 2020 00:21:17

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e8f970a0-7a37-4a74-985a-fc9f5bf4d072'	System	21 Sep 2020 00:21:17
User entered '0'	System	21 Sep 2020 00:21:17

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:14', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e8f970a0-7a37-4a74-985a-fc9f5bf4d072'	System	21 Sep 2020 00:21:17
User entered '20 Sep 2020 20:21'	System	21 Sep 2020 00:21:17

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 6'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:19', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1a772892-3c15-40e6-b24b-37d584e6df8b' User entered 'Yes (Y)'	System	21 Sep 2020 16:03:31
	System	21 Sep 2020 16:03:31

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:24', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1a772892-3c15-40e6-b24b-37d584e6df8b' User entered '98.5'	System	21 Sep 2020 16:03:31
	System	21 Sep 2020 16:03:31

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:28', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1a772892-3c15-40e6-b24b-37d584e6df8b' User entered 'No (N)'	System	21 Sep 2020 16:03:31
	System	21 Sep 2020 16:03:31

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:31', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1a772892-3c15-40e6-b24b-37d584e6df8b' User entered '21 Sep 2020 12:00'	System	21 Sep 2020 16:03:31
	System	21 Sep 2020 16:03:31

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 7'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:23', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '2dc0df8d-a88b-484f-a341-1a2e59539f49' User entered 'Yes (Y)'	System	22 Sep 2020 16:18:34
	System	22 Sep 2020 16:18:34

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:27', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '2dc0df8d-a88b-484f-a341-1a2e59539f49' User entered '98.7'	System	22 Sep 2020 16:18:34
	System	22 Sep 2020 16:18:34

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:29', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '2dc0df8d-a88b-484f-a341-1a2e59539f49'	System	22 Sep 2020 16:18:34
User entered 'No (N)'	System	22 Sep 2020 16:18:34

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:31', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '2dc0df8d-a88b-484f-a341-1a2e59539f49' User entered '22 Sep 2020 12:18'	System	22 Sep 2020 16:18:34
	System	22 Sep 2020 16:18:34

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:21', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a7def7c7-0379-45d4-a059-3d75fd8a6f49'	System	16 Sep 2020 15:25:36
User entered 'None (1)'	System	16 Sep 2020 15:25:36

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:23', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a7def7c7-0379-45d4-a059-3d75fd8a6f49'	System	16 Sep 2020 15:25:36
User entered 'No (N)'	System	16 Sep 2020 15:25:36

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:26', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a7def7c7-0379-45d4-a059-3d75fd8a6f49'	System	16 Sep 2020 15:25:36
User entered 'No (N)'	System	16 Sep 2020 15:25:36

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:31', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a7def7c7-0379-45d4-a059-3d75fd8a6f49'	System	16 Sep 2020 15:25:36
User entered 'None (1)'	System	16 Sep 2020 15:25:36

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:33', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a7def7c7-0379-45d4-a059-3d75fd8a6f49' User entered '16 Sep 2020 11:25'	System	16 Sep 2020 15:25:36
	System	16 Sep 2020 15:25:36

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 11:17'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 13:47'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:51:52', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd21e3b0-022b-4482-9ee1-634c7d800614'	System	17 Sep 2020 13:52:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Sep 2020 13:52:08

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:51:54', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd21e3b0-022b-4482-9ee1-634c7d800614' User entered 'No (N)'	System	17 Sep 2020 13:52:08
	System	17 Sep 2020 13:52:08

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd21e3b0-022b-4482-9ee1-634c7d800614'	System	17 Sep 2020 13:52:08
User entered 'No (N)'	System	17 Sep 2020 13:52:08

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:02', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd21e3b0-022b-4482-9ee1-634c7d800614'	System	17 Sep 2020 13:52:08
User entered 'None (1)'	System	17 Sep 2020 13:52:08

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:06', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd21e3b0-022b-4482-9ee1-634c7d800614' User entered '17 Sep 2020 09:52'	System	17 Sep 2020 13:52:08
	System	17 Sep 2020 13:52:08

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 14:42'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 2'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:37', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '36698f8f-88ae-44a1-81ce-1e4002e14926'	System	18 Sep 2020 13:35:46
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 13:35:46

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:39', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '36698f8f-88ae-44a1-81ce-1e4002e14926' User entered 'No (N)'	System	18 Sep 2020 13:35:46
	System	18 Sep 2020 13:35:46

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:40', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '36698f8f-88ae-44a1-81ce-1e4002e14926' User entered 'No (N)'	System	18 Sep 2020 13:35:46
	System	18 Sep 2020 13:35:46

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:42', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '36698f8f-88ae-44a1-81ce-1e4002e14926'	System	18 Sep 2020 13:35:46
User entered 'None (1)'	System	18 Sep 2020 13:35:46

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:44', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '36698f8f-88ae-44a1-81ce-1e4002e14926' User entered '18 Sep 2020 09:35'	System	18 Sep 2020 13:35:46
	System	18 Sep 2020 13:35:46

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 3'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:01', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'be24613b-e0a7-49cf-b6cc-bbf6bfe7f333'	System	19 Sep 2020 09:10:13
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 09:10:13

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:04', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'be24613b-e0a7-49cf-b6cc-bbf6bfe7f333'	System	19 Sep 2020 09:10:13
User entered 'No (N)'	System	19 Sep 2020 09:10:13

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:06', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'be24613b-e0a7-49cf-b6cc-bbf6bfe7f333' User entered 'No (N)'	System	19 Sep 2020 09:10:13
	System	19 Sep 2020 09:10:13

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:09', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'be24613b-e0a7-49cf-b6cc-bbf6bfe7f333'	System	19 Sep 2020 09:10:13
User entered 'None (1)'	System	19 Sep 2020 09:10:13

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'be24613b-e0a7-49cf-b6cc-bbf6bfe7f333'	System	19 Sep 2020 09:10:13
User entered '19 Sep 2020 05:10'	System	19 Sep 2020 09:10:13

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 4'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 5'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:17', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '829d6dd0-4565-427d-bd56-264f8956d5f7' User entered 'None (1)'	System	21 Sep 2020 00:21:26
	System	21 Sep 2020 00:21:26

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:19', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '829d6dd0-4565-427d-bd56-264f8956d5f7' User entered 'No (N)'	System	21 Sep 2020 00:21:26
	System	21 Sep 2020 00:21:26

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:20', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '829d6dd0-4565-427d-bd56-264f8956d5f7' User entered 'No (N)'	System	21 Sep 2020 00:21:26
	System	21 Sep 2020 00:21:26

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:22', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '829d6dd0-4565-427d-bd56-264f8956d5f7'	System	21 Sep 2020 00:21:26
User entered 'None (1)'	System	21 Sep 2020 00:21:26

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:24', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '829d6dd0-4565-427d-bd56-264f8956d5f7' User entered '20 Sep 2020 20:21'	System	21 Sep 2020 00:21:26
	System	21 Sep 2020 00:21:26

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 6'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:34', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd9355d2-4784-4856-9b1c-746576c3c68b'	System	21 Sep 2020 16:03:50
User entered 'None (1)'	System	21 Sep 2020 16:03:50

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:35', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd9355d2-4784-4856-9b1c-746576c3c68b' User entered 'No (N)'	System	21 Sep 2020 16:03:50
	System	21 Sep 2020 16:03:50

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:37', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd9355d2-4784-4856-9b1c-746576c3c68b' User entered 'No (N)'	System	21 Sep 2020 16:03:50
	System	21 Sep 2020 16:03:50

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:38', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd9355d2-4784-4856-9b1c-746576c3c68b'	System	21 Sep 2020 16:03:50
User entered 'None (1)'	System	21 Sep 2020 16:03:50

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:40', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'dd9355d2-4784-4856-9b1c-746576c3c68b' User entered '21 Sep 2020 12:00'	System	21 Sep 2020 16:03:50
	System	21 Sep 2020 16:03:50

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 7'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:34', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1b9816fc-649b-4cd7-ae61-74f43862ecf0'	System	22 Sep 2020 16:18:44
User entered 'None (1)'	System	22 Sep 2020 16:18:44

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:36', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1b9816fc-649b-4cd7-ae61-74f43862ecf0' User entered 'No (N)'	System	22 Sep 2020 16:18:44
	System	22 Sep 2020 16:18:44

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:38', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1b9816fc-649b-4cd7-ae61-74f43862ecf0' User entered 'No (N)'	System	22 Sep 2020 16:18:44
	System	22 Sep 2020 16:18:44

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:40', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1b9816fc-649b-4cd7-ae61-74f43862ecf0'	System	22 Sep 2020 16:18:44
User entered 'None (1)'	System	22 Sep 2020 16:18:44

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:42', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1b9816fc-649b-4cd7-ae61-74f43862ecf0' User entered '22 Sep 2020 12:18'	System	22 Sep 2020 16:18:44
	System	22 Sep 2020 16:18:44

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:01', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a47b6ce2-ee82-4a32-a134-f309af3e78ae' User entered 'None (0)'	System	16 Sep 2020 15:25:22
	System	16 Sep 2020 15:25:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:03', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a47b6ce2-ee82-4a32-a134-f309af3e78ae' User entered 'None (0)'	System	16 Sep 2020 15:25:22
	System	16 Sep 2020 15:25:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:05', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a47b6ce2-ee82-4a32-a134-f309af3e78ae' User entered 'None (0)'	System	16 Sep 2020 15:25:22
	System	16 Sep 2020 15:25:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:07', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a47b6ce2-ee82-4a32-a134-f309af3e78ae' User entered 'None (0)'	System	16 Sep 2020 15:25:22
	System	16 Sep 2020 15:25:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:10', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a47b6ce2-ee82-4a32-a134-f309af3e78ae' User entered 'None (0)'	System	16 Sep 2020 15:25:22
	System	16 Sep 2020 15:25:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:11', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a47b6ce2-ee82-4a32-a134-f309af3e78ae' User entered 'None (0)'	System	16 Sep 2020 15:25:22
	System	16 Sep 2020 15:25:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:15', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a47b6ce2-ee82-4a32-a134-f309af3e78ae' User entered 'No (N)'	System	16 Sep 2020 15:25:22
	System	16 Sep 2020 15:25:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-16T11:25:17', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'a47b6ce2-ee82-4a32-a134-f309af3e78ae' User entered '16 Sep 2020 11:25'	System	16 Sep 2020 15:25:22
	System	16 Sep 2020 15:25:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 11:17'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 13:47'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:10', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61cdbd29-e00a-4c97-927f-45efb3138251'	System	17 Sep 2020 13:52:28
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	17 Sep 2020 13:52:28

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:13', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61cdbd29-e00a-4c97-927f-45efb3138251' User entered 'None (0)'	System	17 Sep 2020 13:52:28
	System	17 Sep 2020 13:52:28

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:15', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61cbbd29-e00a-4c97-927f-45efb3138251' User entered 'None (0)'	System	17 Sep 2020 13:52:28
	System	17 Sep 2020 13:52:28

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:16', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61cdbd29-e00a-4c97-927f-45efb3138251' User entered 'None (0)'	System	17 Sep 2020 13:52:28
	System	17 Sep 2020 13:52:28

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:18', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61cdbd29-e00a-4c97-927f-45efb3138251' User entered 'None (0)'	System	17 Sep 2020 13:52:28
	System	17 Sep 2020 13:52:28

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:20', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61cbbd29-e00a-4c97-927f-45efb3138251' User entered 'None (0)'	System	17 Sep 2020 13:52:28
	System	17 Sep 2020 13:52:28

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:23', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61cbbd29-e00a-4c97-927f-45efb3138251' User entered 'No (N)'	System	17 Sep 2020 13:52:28
	System	17 Sep 2020 13:52:28

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-17T09:52:25', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61cdbd29-e00a-4c97-927f-45efb3138251' User entered '17 Sep 2020 09:52'	System	17 Sep 2020 13:52:28
	System	17 Sep 2020 13:52:28

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '16 Sep 2020 14:42'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 2'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:47', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc4b3bdc-8350-4bef-bd99-12459814c3a9' User entered 'None (0)'	System	18 Sep 2020 13:36:04
	System	18 Sep 2020 13:36:04

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:49', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc4b3bdc-8350-4bef-bd99-12459814c3a9' User entered 'None (0)'	System	18 Sep 2020 13:36:04
	System	18 Sep 2020 13:36:04

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc4b3bdc-8350-4bef-bd99-12459814c3a9' User entered 'None (0)'	System	18 Sep 2020 13:36:04
	System	18 Sep 2020 13:36:04

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:52', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc4b3bdc-8350-4bef-bd99-12459814c3a9' User entered 'None (0)'	System	18 Sep 2020 13:36:04
	System	18 Sep 2020 13:36:04

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:53', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc4b3bdc-8350-4bef-bd99-12459814c3a9' User entered 'None (0)'	System	18 Sep 2020 13:36:04
	System	18 Sep 2020 13:36:04

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:55', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc4b3bdc-8350-4bef-bd99-12459814c3a9' User entered 'None (0)'	System	18 Sep 2020 13:36:04
	System	18 Sep 2020 13:36:04

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:57', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc4b3bdc-8350-4bef-bd99-12459814c3a9' User entered 'No (N)'	System	18 Sep 2020 13:36:04
	System	18 Sep 2020 13:36:04

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-18T09:35:59', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bc4b3bdc-8350-4bef-bd99-12459814c3a9' User entered '18 Sep 2020 09:35'	System	18 Sep 2020 13:36:04
	System	18 Sep 2020 13:36:04

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 3'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:19', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96ce5649-ed0b-4333-9cbf-6dd7a4d8d7fb'	System	19 Sep 2020 09:10:44
User entered 'No interference with activity (1)'	System	19 Sep 2020 09:10:44

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:22', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96ce5649-ed0b-4333-9cbf-6dd7a4d8d7fb' User entered 'None (0)'	System	19 Sep 2020 09:10:44
	System	19 Sep 2020 09:10:44

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:27', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96ce5649-ed0b-4333-9cbf-6dd7a4d8d7fb' User entered 'None (0)'	System	19 Sep 2020 09:10:44
	System	19 Sep 2020 09:10:44

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:30', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96ce5649-ed0b-4333-9cbf-6dd7a4d8d7fb' User entered 'None (0)'	System	19 Sep 2020 09:10:44
	System	19 Sep 2020 09:10:44

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:32', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96ce5649-ed0b-4333-9cbf-6dd7a4d8d7fb' User entered 'None (0)'	System	19 Sep 2020 09:10:44
	System	19 Sep 2020 09:10:44

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:35', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96ce5649-ed0b-4333-9cbf-6dd7a4d8d7fb' User entered 'None (0)'	System	19 Sep 2020 09:10:44
	System	19 Sep 2020 09:10:44

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:38', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96ce5649-ed0b-4333-9cbf-6dd7a4d8d7fb' User entered 'No (N)'	System	19 Sep 2020 09:10:44
	System	19 Sep 2020 09:10:44

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-19T05:10:41', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96ce5649-ed0b-4333-9cbf-6dd7a4d8d7fb' User entered '19 Sep 2020 05:10'	System	19 Sep 2020 09:10:44
	System	19 Sep 2020 09:10:44

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 4'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 5'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:32', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61b67d61-7af7-4ad2-982e-0ea44af794e6'	System	21 Sep 2020 00:21:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	21 Sep 2020 00:21:49

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:34', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61b67d61-7af7-4ad2-982e-0ea44af794e6' User entered 'None (0)'	System	21 Sep 2020 00:21:49
	System	21 Sep 2020 00:21:49

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:36', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61b67d61-7af7-4ad2-982e-0ea44af794e6' User entered 'None (0)'	System	21 Sep 2020 00:21:49
	System	21 Sep 2020 00:21:49

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:38', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61b67d61-7af7-4ad2-982e-0ea44af794e6' User entered 'None (0)'	System	21 Sep 2020 00:21:49
	System	21 Sep 2020 00:21:49

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:39', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61b67d61-7af7-4ad2-982e-0ea44af794e6' User entered 'None (0)'	System	21 Sep 2020 00:21:49
	System	21 Sep 2020 00:21:49

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:43', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61b67d61-7af7-4ad2-982e-0ea44af794e6' User entered 'None (0)'	System	21 Sep 2020 00:21:49
	System	21 Sep 2020 00:21:49

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:45', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61b67d61-7af7-4ad2-982e-0ea44af794e6' User entered 'No (N)'	System	21 Sep 2020 00:21:49
	System	21 Sep 2020 00:21:49

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-20T20:21:47', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '61b67d61-7af7-4ad2-982e-0ea44af794e6' User entered '20 Sep 2020 20:21'	System	21 Sep 2020 00:21:49
	System	21 Sep 2020 00:21:49

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 6'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:43', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd7952bc7-e634-4e85-84e0-fa1bc299fc0a' User entered 'None (0)'	System	21 Sep 2020 16:04:18
	System	21 Sep 2020 16:04:18

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:44', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd7952bc7-e634-4e85-84e0-fa1bc299fc0a' User entered 'None (0)'	System	21 Sep 2020 16:04:18
	System	21 Sep 2020 16:04:18

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:46', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd7952bc7-e634-4e85-84e0-fa1bc299fc0a' User entered 'None (0)'	System	21 Sep 2020 16:04:18
	System	21 Sep 2020 16:04:18

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:47', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd7952bc7-e634-4e85-84e0-fa1bc299fc0a' User entered 'None (0)'	System	21 Sep 2020 16:04:18
	System	21 Sep 2020 16:04:18

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:48', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd7952bc7-e634-4e85-84e0-fa1bc299fc0a' User entered 'None (0)'	System	21 Sep 2020 16:04:18
	System	21 Sep 2020 16:04:18

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd7952bc7-e634-4e85-84e0-fa1bc299fc0a' User entered 'None (0)'	System	21 Sep 2020 16:04:18
	System	21 Sep 2020 16:04:18

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:51', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd7952bc7-e634-4e85-84e0-fa1bc299fc0a' User entered 'No (N)'	System	21 Sep 2020 16:04:18
	System	21 Sep 2020 16:04:18

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-21T12:00:53', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd7952bc7-e634-4e85-84e0-fa1bc299fc0a' User entered '21 Sep 2020 12:00'	System	21 Sep 2020 16:04:18
	System	21 Sep 2020 16:04:18

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	16 Sep 2020 15:07:59
User entered 'Day 7'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:47', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6ed71d69-0d8f-4632-828f-d5e84b3f539b' User entered 'None (0)'	System	22 Sep 2020 16:19:02
	System	22 Sep 2020 16:19:02

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:48', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6ed71d69-0d8f-4632-828f-d5e84b3f539b' User entered 'None (0)'	System	22 Sep 2020 16:19:02
	System	22 Sep 2020 16:19:02

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6ed71d69-0d8f-4632-828f-d5e84b3f539b' User entered 'None (0)'	System	22 Sep 2020 16:19:02
	System	22 Sep 2020 16:19:02

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:51', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6ed71d69-0d8f-4632-828f-d5e84b3f539b' User entered 'None (0)'	System	22 Sep 2020 16:19:02
	System	22 Sep 2020 16:19:02

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:53', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6ed71d69-0d8f-4632-828f-d5e84b3f539b' User entered 'None (0)'	System	22 Sep 2020 16:19:02
	System	22 Sep 2020 16:19:02

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:55', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6ed71d69-0d8f-4632-828f-d5e84b3f539b' User entered 'None (0)'	System	22 Sep 2020 16:19:02
	System	22 Sep 2020 16:19:02

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:57', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6ed71d69-0d8f-4632-828f-d5e84b3f539b' User entered 'No (N)'	System	22 Sep 2020 16:19:02
	System	22 Sep 2020 16:19:02

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-09-22T12:18:58', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6ed71d69-0d8f-4632-828f-d5e84b3f539b' User entered '22 Sep 2020 12:18'	System	22 Sep 2020 16:19:02
	System	22 Sep 2020 16:19:02

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:07:59

US3722305

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:28:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:07:59

US3722305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	01 Oct 2020 14:53:02

US3722305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '23 Sep 2020'	Taylor Wilson (b) (4)	01 Oct 2020 14:53:02

US3722305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	01 Oct 2020 14:53:02

US3722305

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Taylor Wilson (b) (4)	01 Oct 2020 14:53:02

US3722305

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	01 Oct 2020 14:53:07

US3722305

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'I'	System	01 Oct 2020 14:53:07

US3722305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	01 Oct 2020 14:53:20

US3722305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '01 Oct 2020'	Taylor Wilson (b) (4)	01 Oct 2020 14:53:20

US3722305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	01 Oct 2020 14:53:20

US3722305

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Taylor Wilson (b) (4)	01 Oct 2020 14:53:20

US3722305

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	01 Oct 2020 14:53:26

US3722305

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'I'	System	01 Oct 2020 14:53:26

US3722305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Oct 2020 19:25:19

US3722305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '7 Oct 2020'	Kayla Peay (b) (4)	08 Oct 2020 19:25:19

US3722305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	08 Oct 2020 19:25:19

US3722305

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	08 Oct 2020 19:25:19

US3722305

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Oct 2020 19:25:22

US3722305

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'I'	System	08 Oct 2020 19:25:22

US3722305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Oct 2020 16:56:13

US3722305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '15 Oct 2020'	Kayla Peay (b) (4)	15 Oct 2020 16:56:13

US3722305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Clinic (Clinic)'	Kayla Peay (b) (4)	15 Oct 2020 16:56:13

US3722305

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'VISIT3'	System	15 Oct 2020 16:56:13

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '15 Oct 2020'	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '10:56'	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '15 Oct 2020 10:56'	System	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '98.4' F	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '72'	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'bpm'	System	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '16'	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'breaths/min'	System	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '103'	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'mmHg'	System	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '69'	Kayla Peay (b) (4)	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'mmHg'	System	15 Oct 2020 16:56:37

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29

US3722305

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29

US3722305

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Oct 2020 16:56:44

US3722305

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '15 Oct 2020'	Kayla Peay (b) (4)	15 Oct 2020 16:56:44

US3722305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Oct 2020 16:56:51

US3722305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '15 Oct 2020'	Kayla Peay (b) (4)	15 Oct 2020 16:56:51

US3722305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '11:20'	Kayla Peay (b) (4)	15 Oct 2020 16:56:51

US3722305

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered '15 Oct 2020 11:20'	System	15 Oct 2020 16:56:51

US3722305

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Oct 2020 16:56:53

US3722305

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'I'	System	15 Oct 2020 16:56:53

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 64'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-10-19T00:47:18', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd1432d28-869f-4980-bcdf-dfd869fd1222'	System	19 Oct 2020 04:47:34
User entered 'No (N)'	System	19 Oct 2020 04:47:34

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-10-19T00:47:28', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd1432d28-869f-4980-bcdf-dfd869fd1222'	System	19 Oct 2020 04:47:34
User entered 'No (N)'	System	19 Oct 2020 04:47:34

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-10-19T00:47:32', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd1432d28-869f-4980-bcdf-dfd869fd1222' User entered '19 Oct 2020 00:47:32'	System	19 Oct 2020 04:47:34
	System	19 Oct 2020 04:47:34

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 71'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-10-26T15:19:53', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96c0c307-f049-46e3-98e0-8640d956d41f' User entered 'No (N)'	System	26 Oct 2020 19:20:02
	System	26 Oct 2020 19:20:02

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-10-26T15:19:56', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96c0c307-f049-46e3-98e0-8640d956d41f' User entered 'No (N)'	System	26 Oct 2020 19:20:02
	System	26 Oct 2020 19:20:02

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-10-26T15:19:58', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '96c0c307-f049-46e3-98e0-8640d956d41f' User entered '26 Oct 2020 15:19:58'	System	26 Oct 2020 19:20:02
	System	26 Oct 2020 19:20:02

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 78'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-04T09:31:56', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '416ffa8f-0d84-4560-b502-1fd603835017'	System	04 Nov 2020 14:32:08
User entered 'No (N)'	System	04 Nov 2020 14:32:08

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-04T09:32:02', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '416ffa8f-0d84-4560-b502-1fd603835017'	System	04 Nov 2020 14:32:08
User entered 'No (N)'	System	04 Nov 2020 14:32:08

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-04T09:32:04', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '416ffa8f-0d84-4560-b502-1fd603835017' User entered '04 Nov 2020 09:32:04'	System	04 Nov 2020 14:32:08
	System	04 Nov 2020 14:32:08

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered 'Day 92'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-16T00:01:21', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6bab9895-0925-4c51-8036-b194f1059e55'	System	16 Nov 2020 05:01:58
User entered 'Yes (Y)'	System	16 Nov 2020 05:01:58

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-16T00:01:27', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6bab9895-0925-4c51-8036-b194f1059e55'	System	16 Nov 2020 05:01:58
User entered 'No (N)'	System	16 Nov 2020 05:01:58

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-16T00:01:32', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6bab9895-0925-4c51-8036-b194f1059e55'	System	16 Nov 2020 05:01:58
User entered 'No (N)'	System	16 Nov 2020 05:01:58

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-16T00:01:41', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6bab9895-0925-4c51-8036-b194f1059e55'	System	16 Nov 2020 05:01:58
User entered 'No (N)'	System	16 Nov 2020 05:01:58

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-16T00:01:49', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6bab9895-0925-4c51-8036-b194f1059e55' User entered '16 Nov 2020 00:01:49'	System	16 Nov 2020 05:01:58
	System	16 Nov 2020 05:01:58

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 14:42:03

US3722305

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:24:22
Data entry locked.	System	19 Aug 2020 14:42:03
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 14:42:03

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-23T01:41:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5bdb7c0d-86e9-47ae-b6b1-5268ba7eb10f' User entered 'No (N)'	System	23 Nov 2020 06:41:15
	System	23 Nov 2020 06:41:15

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-23T01:41:09', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5bdb7c0d-86e9-47ae-b6b1-5268ba7eb10f' User entered 'No (N)'	System	23 Nov 2020 06:41:15
	System	23 Nov 2020 06:41:15

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-23T01:41:12', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5bdb7c0d-86e9-47ae-b6b1-5268ba7eb10f' User entered '23 Nov 2020 01:41:12'	System	23 Nov 2020 06:41:15
	System	23 Nov 2020 06:41:15

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-27T00:45:43', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c28cb8b1-60a6-4044-9632-f83649787979' User entered 'No (N)'	System	27 Nov 2020 05:45:58
	System	27 Nov 2020 05:45:58

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-27T00:45:52', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c28cb8b1-60a6-4044-9632-f83649787979' User entered 'No (N)'	System	27 Nov 2020 05:45:58

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-11-27T00:45:56', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c28cb8b1-60a6-4044-9632-f83649787979' User entered '27 Nov 2020 00:45:56'	System	27 Nov 2020 05:45:58
	System	27 Nov 2020 05:45:58

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-04T00:23:08', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '0404849e-5732-426f-988a-05eeaff06f4f' User entered 'No (N)'	System	04 Dec 2020 05:23:40
	System	04 Dec 2020 05:23:40

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-04T00:23:13', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '0404849e-5732-426f-988a-05eeaff06f4f' User entered 'Yes (Y)'	System	04 Dec 2020 05:23:40
	System	04 Dec 2020 05:23:40

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Please 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-04T00:23:22', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '0404849e-5732-426f-988a-05eeaff06f4f'	System	04 Dec 2020 05:23:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 05:23:40

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-04T00:23:31', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '0404849e-5732-426f-988a-05eeaff06f4f' User entered '04 Dec 2020 00:23:31'	System	04 Dec 2020 05:23:40
	System	04 Dec 2020 05:23:40

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-11T06:59:07', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5e8d1903-f1b4-4829-9185-cebd3cf21bc0' User entered 'No (N)'	System	11 Dec 2020 11:59:18
	System	11 Dec 2020 11:59:18

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-11T06:59:13', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5e8d1903-f1b4-4829-9185-cebd3cf21bc0' User entered 'No (N)'	System	11 Dec 2020 11:59:18
	System	11 Dec 2020 11:59:18

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-11T06:59:16', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '5e8d1903-f1b4-4829-9185-cebd3cf21bc0' User entered '11 Dec 2020 06:59:16'	System	11 Dec 2020 11:59:18
	System	11 Dec 2020 11:59:18

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-18T02:39:22', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3378037f-a36d-4817-908c-55d4aa5fa6fa' User entered 'No (N)'	System	18 Dec 2020 07:39:38
	System	18 Dec 2020 07:39:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-18T02:39:31', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3378037f-a36d-4817-908c-55d4aa5fa6fa' User entered 'No (N)'	System	18 Dec 2020 07:39:38
	System	18 Dec 2020 07:39:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-18T02:39:34', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3378037f-a36d-4817-908c-55d4aa5fa6fa' User entered '18 Dec 2020 02:39:34'	System	18 Dec 2020 07:39:38
	System	18 Dec 2020 07:39:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-25T05:10:44', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e007accc-473c-4509-97c7-5238f706a430' User entered 'No (N)'	System	25 Dec 2020 10:10:57
	System	25 Dec 2020 10:10:57

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-25T05:10:50', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e007accc-473c-4509-97c7-5238f706a430'	System	25 Dec 2020 10:10:57
User entered 'No (N)'	System	25 Dec 2020 10:10:57

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2020-12-25T05:10:54', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'e007accc-473c-4509-97c7-5238f706a430' User entered '25 Dec 2020 05:10:54'	System	25 Dec 2020 10:10:57
	System	25 Dec 2020 10:10:57

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-01T01:13:10', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c1d043ad-a27a-4d9c-a928-dcd85d1bbbd5' User entered 'No (N)'	System	01 Jan 2021 06:13:21
	System	01 Jan 2021 06:13:21

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-01T01:13:16', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c1d043ad-a27a-4d9c-a928-dcd85d1bbbd5' User entered 'No (N)'	System	01 Jan 2021 06:13:21
	System	01 Jan 2021 06:13:21

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-01T01:13:18', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c1d043ad-a27a-4d9c-a928-dcd85d1bbbd5' User entered '01 Jan 2021 01:13:18'	System	01 Jan 2021 06:13:21
	System	01 Jan 2021 06:13:21

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-08T00:27:31', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'b462f5d1-43d7-4f2f-b8f6-db7a7f35a419' User entered 'No (N)'	System	08 Jan 2021 05:27:41
	System	08 Jan 2021 05:27:41

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-08T00:27:35', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'b462f5d1-43d7-4f2f-b8f6-db7a7f35a419'	System	08 Jan 2021 05:27:41
User entered 'No (N)'	System	08 Jan 2021 05:27:41

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-08T00:27:38', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'b462f5d1-43d7-4f2f-b8f6-db7a7f35a419' User entered '08 Jan 2021 00:27:38'	System	08 Jan 2021 05:27:41
	System	08 Jan 2021 05:27:41

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-15T00:59:41', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bf5176e7-b02d-4c7b-823a-b4a0d1f3253c' User entered 'No (N)'	System	15 Jan 2021 05:59:53

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-15T00:59:48', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bf5176e7-b02d-4c7b-823a-b4a0d1f3253c' User entered 'No (N)'	System	15 Jan 2021 05:59:53

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-15T00:59:51', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'bf5176e7-b02d-4c7b-823a-b4a0d1f3253c' User entered '15 Jan 2021 00:59:51'	System	15 Jan 2021 05:59:53
	System	15 Jan 2021 05:59:53

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-22T11:38:49', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1ec40690-c357-414f-ac7c-bf1ecf804293' User entered 'No (N)'	System	22 Jan 2021 16:38:58
	System	22 Jan 2021 16:38:58

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-22T11:38:52', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1ec40690-c357-414f-ac7c-bf1ecf804293'	System	22 Jan 2021 16:38:58
User entered 'No (N)'	System	22 Jan 2021 16:38:58

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-22T11:38:54', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1ec40690-c357-414f-ac7c-bf1ecf804293' User entered '22 Jan 2021 11:38:54'	System	22 Jan 2021 16:38:58
	System	22 Jan 2021 16:38:58

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-30T13:53:16', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '7c7e907f-4be2-42da-9d3b-a5084bcbe9af'	System	30 Jan 2021 18:53:24
User entered 'No (N)'	System	30 Jan 2021 18:53:24

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-30T13:53:19', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '7c7e907f-4be2-42da-9d3b-a5084bcbe9af'	System	30 Jan 2021 18:53:24
User entered 'No (N)'	System	30 Jan 2021 18:53:24

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-01-30T13:53:21', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '7c7e907f-4be2-42da-9d3b-a5084bcbe9af' User entered '30 Jan 2021 13:53:21'	System	30 Jan 2021 18:53:24
	System	30 Jan 2021 18:53:24

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-05T00:51:41', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd3b638e4-35fd-4450-a3c0-d0c322203a11' User entered 'No (N)'	System	05 Feb 2021 05:51:50
	System	05 Feb 2021 05:51:50

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-05T00:51:43', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd3b638e4-35fd-4450-a3c0-d0c322203a11' User entered 'No (N)'	System	05 Feb 2021 05:51:50
	System	05 Feb 2021 05:51:50

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-05T00:51:46', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd3b638e4-35fd-4450-a3c0-d0c322203a11' User entered '05 Feb 2021 00:51:46'	System	05 Feb 2021 05:51:50
	System	05 Feb 2021 05:51:50

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-12T04:21:54', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '749164ff-21a9-4cf6-9d1d-3fcc81352c0f' User entered 'No (N)'	System	12 Feb 2021 09:22:01
	System	12 Feb 2021 09:22:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-12T04:21:56', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '749164ff-21a9-4cf6-9d1d-3fcc81352c0f' User entered 'No (N)'	System	12 Feb 2021 09:22:01
	System	12 Feb 2021 09:22:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-12T04:21:59', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '749164ff-21a9-4cf6-9d1d-3fcc81352c0f' User entered '12 Feb 2021 04:21:59'	System	12 Feb 2021 09:22:01
	System	12 Feb 2021 09:22:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-19T00:01:31', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3b7f7cc9-bb87-4f14-85d8-153c72a44e7d' User entered 'No (N)'	System	19 Feb 2021 05:02:27
	System	19 Feb 2021 05:02:27

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-19T00:01:34', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3b7f7cc9-bb87-4f14-85d8-153c72a44e7d' User entered 'No (N)'	System	19 Feb 2021 05:02:27
	System	19 Feb 2021 05:02:27

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-19T00:01:37', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '3b7f7cc9-bb87-4f14-85d8-153c72a44e7d' User entered '19 Feb 2021 00:01:37'	System	19 Feb 2021 05:02:27
	System	19 Feb 2021 05:02:27

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-27T21:03:04-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c69a060a-f7ac-415b-91e5-18eba77684c2'	System	28 Feb 2021 02:05:35
User entered 'No (N)'	System	28 Feb 2021 02:05:35

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-27T21:03:07-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c69a060a-f7ac-415b-91e5-18eba77684c2'	System	28 Feb 2021 02:05:35
User entered 'No (N)'	System	28 Feb 2021 02:05:35

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-27T21:03:10-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c69a060a-f7ac-415b-91e5-18eba77684c2' User entered '28 Feb 2021 02:03:10'	System	28 Feb 2021 02:05:35
	System	28 Feb 2021 02:05:35

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-05T15:29:33-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '59e8981a-61b3-4173-80c7-d0b058de8336'	System	05 Mar 2021 20:29:41
User entered 'No (N)'	System	05 Mar 2021 20:29:41

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-05T15:29:35-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '59e8981a-61b3-4173-80c7-d0b058de8336'	System	05 Mar 2021 20:29:41
User entered 'No (N)'	System	05 Mar 2021 20:29:41

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-05T15:29:39-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '59e8981a-61b3-4173-80c7-d0b058de8336'	System	05 Mar 2021 20:29:41
User entered '05 Mar 2021 20:29:39'	System	05 Mar 2021 20:29:41

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-12T12:10:39-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd234b058-0809-4440-93b1-9dd0ebccd281'	System	15 Mar 2021 18:04:19
User entered 'No (N)'	System	15 Mar 2021 18:04:19

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-12T12:10:41-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd234b058-0809-4440-93b1-9dd0ebccd281'	System	15 Mar 2021 18:04:19
User entered 'No (N)'	System	15 Mar 2021 18:04:19

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-12T12:10:45-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd234b058-0809-4440-93b1-9dd0ebccd281'	System	15 Mar 2021 18:04:19
User entered '12 Mar 2021 17:10:45'	System	15 Mar 2021 18:04:19

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-19T04:01:50-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce570d5a-7caf-42a5-82ea-8588888a7394'	System	19 Mar 2021 08:02:16
User entered 'No (N)'	System	19 Mar 2021 08:02:16

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-19T04:01:58-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce570d5a-7caf-42a5-82ea-8588888a7394'	System	19 Mar 2021 08:02:16
User entered 'No (N)'	System	19 Mar 2021 08:02:16

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-19T04:02:02-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'ce570d5a-7caf-42a5-82ea-8588888a7394'	System	19 Mar 2021 08:02:16
User entered '19 Mar 2021 08:02:02'	System	19 Mar 2021 08:02:16

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-26T00:50:42-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd50d2f06-f284-4fbb-9c46-f4a0f372f2a7'	System	26 Mar 2021 04:50:52
User entered 'No (N)'	System	26 Mar 2021 04:50:52

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-26T00:50:46-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd50d2f06-f284-4fbb-9c46-f4a0f372f2a7'	System	26 Mar 2021 04:50:52
User entered 'No (N)'	System	26 Mar 2021 04:50:52

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-03-26T00:50:50-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'd50d2f06-f284-4fbb-9c46-f4a0f372f2a7'	System	26 Mar 2021 04:50:52
User entered '26 Mar 2021 04:50:50'	System	26 Mar 2021 04:50:52

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-04-02T07:34:05-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '7c0ae4c3-195b-4f8c-91dc-5d86f4da5134' User entered 'No (N)'	System	02 Apr 2021 11:34:25
	System	02 Apr 2021 11:34:25

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-04-02T07:34:10-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '7c0ae4c3-195b-4f8c-91dc-5d86f4da5134' User entered 'No (N)'	System	02 Apr 2021 11:34:25
	System	02 Apr 2021 11:34:25

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-04-02T07:34:14-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '7c0ae4c3-195b-4f8c-91dc-5d86f4da5134'	System	02 Apr 2021 11:34:25
User entered '02 Apr 2021 11:34:14'	System	02 Apr 2021 11:34:25

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-09T16:36:38-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6c572dae-87f7-49b1-8e17-e1718f5eff3a' User entered 'No (N)'	System	09 Apr 2021 20:37:14
	System	09 Apr 2021 20:37:14

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-09T16:36:58-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6c572dae-87f7-49b1-8e17-e1718f5eff3a' User entered 'No (N)'	System	09 Apr 2021 20:37:14

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-09T16:37:11-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '6c572dae-87f7-49b1-8e17-e1718f5eff3a' User entered '09 Apr 2021 16:37:11'	System	09 Apr 2021 20:37:14
	System	09 Apr 2021 20:37:14

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-17T10:44:20-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9b6d8905-72a3-4306-8d7c-0f1cba2b3586'	System	17 Apr 2021 14:44:38
User entered 'No (N)'	System	17 Apr 2021 14:44:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-17T10:44:32-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9b6d8905-72a3-4306-8d7c-0f1cba2b3586'	System	17 Apr 2021 14:44:38
User entered 'No (N)'	System	17 Apr 2021 14:44:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-17T10:44:35-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '9b6d8905-72a3-4306-8d7c-0f1cba2b3586'	System	17 Apr 2021 14:44:38
User entered '17 Apr 2021 10:44:35'	System	17 Apr 2021 14:44:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-23T15:20:59-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1adc6b15-4a6c-4369-8acd-0d8aff27467b'	System	23 Apr 2021 19:21:12
User entered 'No (N)'	System	23 Apr 2021 19:21:12

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-23T15:21:03-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1adc6b15-4a6c-4369-8acd-0d8aff27467b'	System	23 Apr 2021 19:21:12
User entered 'No (N)'	System	23 Apr 2021 19:21:12

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-23T15:21:06-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: '1adc6b15-4a6c-4369-8acd-0d8aff27467b'	System	23 Apr 2021 19:21:12
User entered '23 Apr 2021 15:21:06'	System	23 Apr 2021 19:21:12

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[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 (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-30T00:38:27-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c36e38e0-6583-4e6d-ab7e-e24d5a0f84ca' User entered 'No (N)'	System	30 Apr 2021 04:38:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

Have you been exposed to someone with 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 (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-30T00:38:32-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c36e38e0-6583-4e6d-ab7e-e24d5a0f84ca' User entered 'No (N)'	System	30 Apr 2021 04:38:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97D01EAC-52D7-4D7F-96A9-E2FE6CC7FE47)', Time: '2021-04-30T00:38:35-04:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'c36e38e0-6583-4e6d-ab7e-e24d5a0f84ca' User entered '30 Apr 2021 00:38:35'	System	30 Apr 2021 04:38:38
	System	30 Apr 2021 04:38:38

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 22:50:01

US3722305

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:28:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:50:01
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 22:50:01

US3722305

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:28:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:05:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-27T21:03:15-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'df595965-bced-45f3-a273-6fcd2fa97377'	System	28 Feb 2021 02:06:30
User entered 'Yes (Y)'	System	28 Feb 2021 02:06:30

US3722305

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:28:31

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:05:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-27T21:03:25-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'df595965-bced-45f3-a273-6fcd2fa97377'	System	28 Feb 2021 02:06:30
User entered 'No (N)'	System	28 Feb 2021 02:06:30

US3722305

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:28:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:05:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A25B9C5-E12B-4EBF-957C-ABCFD4F0E97F)', Time: '2021-02-27T21:03:30-05:00', User OID: 'PatientReportedOutcome (US3722305)', ODM File OID: 'df595965-bced-45f3-a273-6fcd2fa97377'	System	28 Feb 2021 02:06:30
User entered '28 Feb 2021 02:03:30'	System	28 Feb 2021 02:06:30

US3722305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Marlee Smith (b) (4)	23 Nov 2020 20:45:38

US3722305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered '11 Nov 2020'	Marlee Smith (b) (4)	23 Nov 2020 20:45:38

US3722305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	23 Nov 2020 20:45:38

US3722305

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered empty.	Marlee Smith (b) (4)	23 Nov 2020 20:45:38

US3722305

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:43:44
User entered 'Yes (Y)'	Marlee Smith (b) (4)	23 Nov 2020 20:45:41

US3722305

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:51:29
User entered 'I'	System	23 Nov 2020 20:45:41

US3722305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:27
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Amy Ford (b) (4)	12 Dec 2020 18:22:00

US3722305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:27
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '12 Dec 2020'	Amy Ford (b) (4)	12 Dec 2020 18:22:00

US3722305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:27
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	12 Dec 2020 18:22:00

US3722305

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:27
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Amy Ford (b) (4)	12 Dec 2020 18:22:00

US3722305

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:27
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Amy Ford (b) (4)	12 Dec 2020 18:22:06

US3722305

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:26:27
User entered 'I'	System	12 Dec 2020 18:22:06

US3722305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:31:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Jan 2021 19:09:36

US3722305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:31:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '12 Jan 2021'	Taylor Wilson (b) (4)	12 Jan 2021 19:09:36

US3722305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:31:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	12 Jan 2021 19:09:36

US3722305

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:31:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Taylor Wilson (b) (4)	12 Jan 2021 19:09:36

US3722305

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:31:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Jan 2021 19:09:41

US3722305

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:31:06
User entered '1'	System	12 Jan 2021 19:09:41

US3722305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:10:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Marlee Smith (b) (4)	10 Feb 2021 18:26:27

US3722305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:10:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '10 Feb 2021'	Marlee Smith (b) (4)	10 Feb 2021 18:26:27

US3722305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:10:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	10 Feb 2021 18:26:27

US3722305

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:10:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Marlee Smith (b) (4)	10 Feb 2021 18:26:27

US3722305

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:10:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Marlee Smith (b) (4)	10 Feb 2021 18:26:32

US3722305

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:10:44
User entered '1'	System	10 Feb 2021 18:26:32

US3722305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Marlee Smith (b) (4)	01 Mar 2021 15:26:37

US3722305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '1 Mar 2021'	Marlee Smith (b) (4)	01 Mar 2021 15:26:37

US3722305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	01 Mar 2021 15:26:37

US3722305

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered 'VISIT4'	System	01 Mar 2021 15:26:37

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '1 Mar 2021'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '10:03'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '1 Mar 2021 10:03'	System	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '98' F	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered 'Oral (Oral)'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered empty.	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '88'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered 'bpm'	System	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '17'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered 'breaths/min'	System	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '105'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered 'mmHg'	System	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '69'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered 'mmHg'	System	30 Mar 2021 17:36:27

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23

US3722305

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:28:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23

US3722305

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'No (N)'	Marlee Smith (b) (4)	01 Mar 2021 15:26:41

US3722305

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:28:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered empty.	Marlee Smith (b) (4)	01 Mar 2021 15:26:41

US3722305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Marlee Smith (b) (4)	01 Mar 2021 15:26:50

US3722305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '1 Mar 2021'	Marlee Smith (b) (4)	01 Mar 2021 15:26:50

US3722305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered '10:05'	Marlee Smith (b) (4)	01 Mar 2021 15:26:50

US3722305

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered '1 Mar 2021 10:05'	System	01 Mar 2021 15:26:50

US3722305

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:31:16
User entered 'Yes (Y)'	Marlee Smith (b) (4)	01 Mar 2021 15:26:55

US3722305

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:02:23
User entered 'I'	System	01 Mar 2021 15:26:55

US3722305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered '12 Apr 2021'	Taylor Wilson (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	

US3722305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	

US3722305

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:28:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Taylor Wilson (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	

US3722305

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Apr 2021 15:00:45
	(b) (4)	

US3722305

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:28:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:00:45

US3722305

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

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4) (b) (4)	11 Jan 2021 22:07:34

US3722305

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

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '11 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	11 Jan 2021 22:07:34

US3722305

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

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	11 Jan 2021 22:07:34

US3722305

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

Form: Visit Date

Generated On: 12 Aug 2021 13:28:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 22:07:34

US3722305

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '11 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	11 Jan 2021 22:07:46

US3722305

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:05:01

US3722305

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
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	12 Jan 2021 13:28:58
User entered 'Yes (Y)' reason for change: Data Entry Error	System	12 Jan 2021 13:28:58
User opened query 'Data is required. Please complete.' (Site from System).	Marlee Smith (b) (4)	12 Jan 2021 13:28:58
User entered empty.	(b) (4)	
	System	11 Jan 2021 22:07:46
	Marlee Smith (b) (4)	11 Jan 2021 22:07:46
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:05:01

US3722305

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	12 Jan 2021 13:28:58
User entered empty.	(b) (4)	
	Marlee Smith (b) (4)	11 Jan 2021 22:07:46
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	12 Jan 2021 13:28:58
User entered empty.	(b) (4)	
	Marlee Smith (b) (4)	11 Jan 2021 22:07:46
	(b) (4)	

US3722305

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	System	20 Jan 2021 07:41:30
User entered empty.	Marlee Smith (b) (4)	12 Jan 2021 13:28:58
	(b) (4)	
	Marlee Smith (b) (4)	11 Jan 2021 22:07:46
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	System	20 Jan 2021 07:41:30
User entered empty.	Marlee Smith (b) (4)	12 Jan 2021 13:28:58
	(b) (4)	
	Marlee Smith (b) (4)	11 Jan 2021 22:07:46
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	12 Jan 2021 13:28:58
User entered empty.	(b) (4)	
	Marlee Smith (b) (4)	11 Jan 2021 22:07:46
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User entered empty.	System	11 Jan 2021 22:07:46

US3722305

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

Form: Unblinding

Generated On: 12 Aug 2021 13:28:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User entered empty.	System	11 Jan 2021 22:07:46

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Marlee Smith (b) (4)	11 Jan 2021 22:08:03

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '11 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	11 Jan 2021 22:08:03

US3722305

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '10:46'	(b) (4) Marlee Smith (b) (4) (b) (4)	11 Jan 2021 22:08:03

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:28:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User entered '11 Jan 2021 10:46'	System	11 Jan 2021 22:08:03

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:28:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	11 Jan 2021 22:08:11

US3722305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:28:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '11 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	11 Jan 2021 22:08:11

US3722305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:28:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '10:48'	(b) (4) Marlee Smith (b) (4) (b) (4)	11 Jan 2021 22:08:11

US3722305

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:28:31

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:28:30
User entered '11 Jan 2021 10:48'	System	11 Jan 2021 22:08:11

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:28:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'No (N)'	Sara Poff (b) (4)	17 Feb 2021 12:48:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:25:16
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 10:32:37
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'Completed' (Site from DM).	Sara Poff (b) (4) (b) (4)	14 Apr 2021 17:47:10
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 15:12:59
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2 Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, Diary Dose 2 Day 1 Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this 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)	12 Mar 2021 07:57:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 2 Pain at Marlee Smith Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, Diary Dose 2 Day 1 Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	(b) (4)	09 Mar 2021 18:01:32
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2 Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, Diary Dose 2 Day 1 Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this 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)	27 Jan 2021 10:21:43
User closed query 'Per CDM : In Diary Dose 2 Temperature day, it was noted that medication was taken to treat pain or fever, however, no corresponding ConMed is recorded in ConMed page. Please review and reconcile. (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:01:15
Query 'Per CDM : In Diary Dose 2 Temperature day, it was noted that medication was taken to treat pain or fever, however, no corresponding ConMed is recorded in ConMed page. Please review and reconcile. answered with 'updated' (Site from DM).	(b) (4)	11 Nov 2020 21:56:17
User opened query 'Per CDM : In Diary Dose 2 Temperature day, it was noted that medication was taken to treat pain or fever, however, no corresponding ConMed is recorded in ConMed page. Please review and reconcile. (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 04:38:52
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:42:53

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 14:44:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:44:23
Data point term sent to Coder	System	19 Aug 2020 14:43:53
User entered 'Levothyroxine'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:43:38

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'hypothyroidism'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered '88'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 07:23:36
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	18 Nov 2020 18:13:49
User entered 'ug (ug)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	18 Nov 2020 18:13:41
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:16:00
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:43:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'once daily (QD)'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'Oral (ORAL)'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:30:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 14:43:38
User entered 'un UNK 2010'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered '0'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	19 Aug 2020 14:43:38
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 14:43:38

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 14:43:38

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:28:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 14:43:38

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: AMITRIPTYLINE HYDROCHLORIDE, PRODUCTSYNONYM: ELAVIL [AMITRIPTYLINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Sep 2020 07:34:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
Data point term sent to Coder	System	19 Aug 2020 14:44:56
User entered 'elevil'	Kayla Peay (b) (4) (b) (4)	19 Aug 2020 14:44:37

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'migraine headaches'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered '25'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'mg (mg)'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'once daily (QD)'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'Oral (ORAL)'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:30:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 14:44:37
User entered 'un UNK 2019'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered '0'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	19 Aug 2020 14:44:37
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 14:44:37

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 14:44:37

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:28:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 14:44:37

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Mar 2021 18:18:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 18:18:39
Data point term sent to Coder Coding entries removed.	System Marlee Smith (b) (4)	09 Mar 2021 18:02:46 09 Mar 2021 18:02:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Aug 2020 20:23:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:23:40
Data point term sent to Coder User entered 'Tylenol'	System Amy Ford (b) (4)	31 Aug 2020 20:22:56 31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'No (N)'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'HEADACHE, pain at injection site' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	09 Mar 2021 18:02:13
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) (6)	20 Nov 2020 07:24:03
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 'does not meet criteria' (Site from DM).	Marlee Smith (b) (4)	18 Nov 2020 17:33:58
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[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 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) (6)	05 Oct 2020 08:16:40
User entered 'headache'	Amy Ford (b) (4) (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '325'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'mg (mg)'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'as needed (PRN)'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Oral (ORAL)'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '20 Aug 2020'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '0'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'No (N)'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 18:02:13
User entered '20 Aug 2020'	Marlee Smith (b) (4)	31 Aug 2020 20:22:27
	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Amy Ford (b) (4)	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User entered empty.	System	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User entered empty.	System	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:28:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:13
User entered empty.	System	31 Aug 2020 20:22:27

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 18:04:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:04:38
Data point term sent to Coder Coding entries removed.	System Marlee Smith (b) (4) (b) (4)	09 Mar 2021 18:03:47 09 Mar 2021 18:02:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:58:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:58:36
Data point term sent to Coder User entered 'ibuprofen'	System Marlee Smith (b) (4) (b) (4)	11 Nov 2020 21:57:57 11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'No (N)'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'HEADACHE, pain at injection site' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	09 Mar 2021 18:02:47
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.	(b) (4), (b) (6)	04 Mar 2021 19:04:16
' (Site from DM).		
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.	Marlee Smith (b) (4)	03 Mar 2021 19:47:02
' answered with 'does not meet AE criteria' (Site from DM).	(b) (4)	

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '200'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'mg (mg)'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'as needed (PRN)'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered empty.	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '17 Sep 2020'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '0'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'No (N)'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered '20 Sep 2020'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
User entered 'Yes (Y)'	Marlee Smith (b) (4)	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User entered empty.	System	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User entered empty.	System	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:28:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:14
User entered empty.	System	11 Nov 2020 21:57:13

US3722305

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:28:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:55:27
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	19 Aug 2020 14:44:46
	(b) (4)	