

US3672092 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:03:53

All time stamps listed in this document are displayed in GMT

US3672092

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Participant ID

US3672092

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

US3672092

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3672092

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 21:36:07

Generated On: 11 Aug 2021 23:03:53

Condition	OSTEOARTHRITIS JOINT PAIN
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 21:36:07

Generated On: 11 Aug 2021 23:03:53

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN JUL 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUL 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 21:36:07

Generated On: 11 Aug 2021 23:03:53

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:40
Height (xxx.x)	173 cm
Weight (xxx.x)	75.8 kg
BMI (xxx.x)	25.32661 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
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) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 19:48:34

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Date of assessment (*dd MMM yyyy*) 13 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*) UN JUL 2018

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:48:34

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:48:34

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103829

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) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

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)	13 AUG 2020
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:48
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

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)	13 AUG 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:08
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 11:35

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

13 AUG 2020 11:10

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:36	13 AUG 2020 10:36
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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

97.6 °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

13 AUG 2020 12:07

PC Open Date & Time

13 AUG 2020 11:55

PC Close Date & Time

13 AUG 2020 14:25

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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

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 13 AUG 2020 15:20

PC Close Date & Time 14 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:03:53

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

98.2 °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

14 AUG 2020 21:28

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

15 AUG 2020 18:05

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

16 AUG 2020 16:10

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:03:53

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

98.2 °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

17 AUG 2020 20:42

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 09:59

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 15:25

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:07

PC Open Date & Time

13 AUG 2020 11:55

PC Close Date & Time

13 AUG 2020 14:25

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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 ☐

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.**

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

PC Open Date & Time

13 AUG 2020 15:20

PC Close Date & Time

14 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

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

14 AUG 2020 21:28

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

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

15 AUG 2020 18:05

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

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

16 AUG 2020 16:10

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

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

17 AUG 2020 20:42

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

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

19 AUG 2020 09:59

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

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

19 AUG 2020 15:26

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 12:08
PC Open Date & Time	13 AUG 2020 11:55
PC Close Date & Time	13 AUG 2020 14:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

13 AUG 2020 15:20

PC Close Date & Time

14 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 21:29
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

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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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

		Yes <input type="checkbox"/>
PC Time stamp	15 AUG 2020 18:05	
PC Open Date & Time	15 AUG 2020 12:00	
PC Close Date & Time	16 AUG 2020 11:59	

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 16:10
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:43
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 09:59
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

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 ☒

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 15:26
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3672092

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

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)	09 SEP 2020
Time of assessment (00:00-23:59)	17:01 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 17:01
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

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 SWELLING AT INJECTION SITE

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3672092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 SEP 2020

Collection time (00:00-23:59)

17:29 (24 HR)

Collection date and time (derived)

09 SEP 2020 17:29

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:29	09 SEP 2020 17:29
Nasopharyngeal Swab 2	No		

US3672092

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:48:34

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:04
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672092

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

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.

US3672092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	10:18 (24 HR)
Collection date and time (derived)	8 OCT 2020 10:18

US3672092

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:49:22

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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	16 OCT 2020 10:28:17
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

23 OCT 2020 13:01:58

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 09:41:24

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 17:26:35

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 13:48:05
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

22 NOV 2020 17:51:09

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 10:51:37
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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	06 DEC 2020 15:16:55
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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	12 DEC 2020 11:05:24
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

19 DEC 2020 13:28:22

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

26 DEC 2020 11:11:46

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 11:18:43

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 152

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

16 JAN 2021 13:53:12

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 09:41:13

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

30 JAN 2021 09:19:24

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 11:26:11

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 11:23:15

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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	20 FEB 2021 12:45:48
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

27 FEB 2021 18:26:10

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

07 MAR 2021 13:38:11

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 09:25:04

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

21 MAR 2021 12:24:36

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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	04 APR 2021 10:53:50
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

11 APR 2021 15:35:28

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 06:05:52

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

25 APR 2021 09:47:00

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 15:39:37

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2021 00:01
Patient Cloud Close Date & Time	23 JUN 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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°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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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°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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 467

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 516

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 <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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 <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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 MAR 2022 00:01
Patient Cloud Close Date & Time	30 MAR 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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 ☐

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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°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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3672092

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:03:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 18:26:19

US3672092

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3672092

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672092

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3672092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

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.

US3672092

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672092

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:03:53

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"/>

US3672092

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 23:03:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3672092

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

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

Visit date (dd MMM yyyy)	29 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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US3672092

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:45:01

Generated On: 11 Aug 2021 23:03:53

Date of updated informed consent (*dd MMM yyyy*) 29 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*) 29 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 _____

US3672092

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

29 JAN 2021 14:00

US3672092

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JAN 2021
Collection time (00:00 - 23:59)	13:12
Collection Date and Time (derived)	29 JAN 2021 13:12

US3672092

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

AEID	
Adverse event	SWELLING AT INJECTION SITE (L)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

AEID

Adverse event

REDNESS AT INJECTION SITE
(L)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

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

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

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

Yes ☒

No ☐

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

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS (JOINTS)

Dose per administration 800

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

TWO TIMES WEEKLY

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

	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 2014	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication REDNESS AND SWELLING AT
INJECTION SITE.

Dose per administration 10

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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US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

	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)	25 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)		27 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3672092

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:36:07

Generated On: 11 Aug 2021 23:03:53

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3672092

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 17:53:14

Generated On: 11 Aug 2021 23:03:53

Date of dosing discontinuation (dd MMM yyyy) 9 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE#1, AE #2
---	-------------

US3672092

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:03:53

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

US3672092 (Prod: Coastal Carolina Research Center)

US3672092

Form: Participant Creation

Generated On: 11 Aug 2021 23:03:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'US3672092'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:44:31

US3672092

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:29:24

US3672092

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:44:32

US3672092

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[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 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:29:24

US3672092

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'SCRN'	System	13 Aug 2020 15:29:24

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:44:32

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	15 Oct 2020 18:55:04
User entered '52' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 18:55:04
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	13 Aug 2020 15:30:13
User entered '58'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'YEARS'	System	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '52'	System	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:03:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:29:56

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'Aug 2020'	System	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '2020'	System	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:44:32

US3672092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:03:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '1'	System	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:30:03

US3672092

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 23:03:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:14:53

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:36:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 20:11:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 20:11:53
Data point term sent to Coder	System	17 Mar 2021 20:11:11
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 20:10:35
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 20:10:35
User entered 'osteoarthritis JOINT PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:10:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:53:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:53:35
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:07:59
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'condition and location updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:49:42
Data point term sent to Coder	System	28 Oct 2020 16:49:32

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

Condition

Audit	User	Time (GMT)
User entered 'Generalized JOINT PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:49:29
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:32:56
User closed query 'Per MM, please review and update the term to reflect the underlying etiology if known' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 18:57:26
Data point term sent to Coder	System	19 Oct 2020 20:37:24
Query 'Per MM, please review and update the term to reflect the underlying etiology if known' answered with 'condition updated per query' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 20:36:59
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 20:36:51
User entered 'JOINT PAIN / arthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:36:51
User opened query 'Per MM, please review and update the term to reflect the underlying etiology if known' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 20:07:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 13:17:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 13:17:20
Data point term sent to Coder	System	14 Aug 2020 13:16:18
User entered 'Joint Pain'	(b) (4), (b) (6)	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'Jan 2014'	System	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '2014'	System	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered empty.	System	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered empty.	System	14 Aug 2020 13:15:31

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:08:20
Query 'Per MM, please include the underlying condition that led to the procedure. ' answered with 'ROUTINE ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:00:36
User opened query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 19:51:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 13:18:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 13:18:24
Data point term sent to Coder	System	14 Aug 2020 13:17:20
User entered 'Cholecystectomy'	(b) (4), (b) (6)	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'UN Jul 2019' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 13:17:26
User entered 'un UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'UN Jul 2019' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	14 Aug 2020 13:17:26
User entered 'un UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'Jul 2019'	System	14 Aug 2020 13:17:26
User entered 'Jan 2019'	System	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '2019'	System	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'Jul 2019'	System	14 Aug 2020 13:17:26
User entered 'Jan 2019'	System	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '2019'	System	14 Aug 2020 13:16:45

US3672092

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 20:38:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 20:38:35
Data point term sent to Coder	System	19 Oct 2020 20:37:23
User entered 'post-menopausal'	(b) (4), (b) (6)	19 Oct 2020 20:36:23

US3672092

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:36:23

US3672092

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:36:23

US3672092

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:36:23

US3672092

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:36:23

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:36:23

US3672092

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'Jan 2018'	System	19 Oct 2020 20:36:23

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '2018'	System	19 Oct 2020 20:36:23

US3672092

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered empty.	System	19 Oct 2020 20:36:23

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered empty.	System	19 Oct 2020 20:36:23

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '13 Aug 2020' reason for change: Data Entry Error	System	14 Aug 2020 13:26:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 13:26:39
User entered '13 ' (non-conformant).	(b) (4)	
	System	14 Aug 2020 13:25:02
	(b) (4), (b) (6)	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:26:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 13:26:39
User entered '10:40' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:26:39
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '13 Aug 2020 10:40'	System	14 Aug 2020 13:26:39
User entered empty.	System	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	14 Aug 2020 13:26:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 13:26:39
User entered '173' cm reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:26:39
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02
DataPoint set to visible.	System	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	14 Aug 2020 13:26:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 13:26:39
User entered '75.8' kg reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:26:39
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02
DataPoint set to visible.	System	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
Amendment Manager: User entered '25.32661'	System	16 Sep 2020 23:55:09
User entered '25.3'	System	14 Aug 2020 13:26:39
User entered empty.	System	14 Aug 2020 13:25:02
DataPoint set to visible.	System	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'kg/m2'	System	14 Aug 2020 13:26:39
User entered empty.	System	14 Aug 2020 13:25:02
DataPoint set to visible.	System	13 Aug 2020 15:30:13

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	14 Aug 2020 13:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 13:34:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 13:34:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	14 Aug 2020 13:34:11
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4) System	14 Aug 2020 13:35:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:35:02
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	14 Aug 2020 13:34:11
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 13:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 13:34:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'bpm'	System	14 Aug 2020 13:34:11
User entered empty.	System	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	14 Aug 2020 13:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 13:34:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'breaths/min'	System	14 Aug 2020 13:34:11
User entered empty.	System	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 13:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 13:34:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'mmHg'	System	14 Aug 2020 13:34:11
User entered empty.	System	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 13:34:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 13:34:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:34:11
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:25:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'mmHg'	System	14 Aug 2020 13:34:11
User entered empty.	System	14 Aug 2020 13:25:02

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29

US3672092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29

US3672092

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:37:32

US3672092

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 18:09:14
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 18:02:06
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 13:37:32

US3672092

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:03:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:43:32

US3672092

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:43:32

US3672092

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:03:53

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:47:41
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'updated in medical history' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 20:37:16
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 23:29:32
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	14 Aug 2020 13:43:32

US3672092

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:43:32

US3672092

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:43:32

US3672092

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:03:53

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:43:32

US3672092

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'UN Jul 2018'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:43:32

US3672092

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:03:53

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:43:32

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:47:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
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	14 Aug 2020 13:47:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:47:42
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 13:47:26
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:47:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:47:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User closed query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System).	(b) (4) System	15 Oct 2020 19:01:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 19:01:00
User opened query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System).	System	14 Aug 2020 13:47:26
User entered (b) (6)	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:03:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:47:26

US3672092

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 13:48:20

US3672092

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 13:48:20

US3672092

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 13:48:20

US3672092

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'VISIT1'	System	14 Aug 2020 13:48:20

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:16:22

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:08:32
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:08:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 15:16:22
User entered '103829' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:16:22

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:16:22

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:49:52

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:49:52

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:49:52

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:49:52

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:49:52

US3672092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:06:24
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:59:29

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:03:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:03:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	System	14 Aug 2020 13:54:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 13:54:28
User entered 'BD' (non-conformant).		
	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:03:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:03:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	System	14 Aug 2020 13:54:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 13:54:28
User entered 'BD' (non-conformant).		
	System	14 Aug 2020 13:52:42
	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '10:48'	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '13 Aug 2020 10:48'	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '98.1' F	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 13:54:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	14 Aug 2020 13:54:09
User entered '53' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:54:09
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:52:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'bpm'	System	14 Aug 2020 13:54:09
User entered empty.	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 13:54:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	14 Aug 2020 13:54:09
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:54:09
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:52:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'breaths/min'	System	14 Aug 2020 13:54:09
User entered empty.	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 13:54:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	14 Aug 2020 13:54:09
User entered '129' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:54:09
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:52:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'mmHg'	System	14 Aug 2020 13:54:09
User entered empty.	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 13:54:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	14 Aug 2020 13:54:09
User entered '87' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 13:54:09
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:52:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'mmHg'	System	14 Aug 2020 13:54:09
User entered empty.	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:03:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:03:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	System	14 Aug 2020 13:54:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 13:54:28
User entered 'BD' (non-conformant).		
	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4)	
	(b) (4), (b) (6)	16 Aug 2020 23:01:08
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 13:52:42
User entered '12:08'	(b) (4), (b) (6)	14 Aug 2020 13:52:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '13 Aug 2020 12:08'	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '97.6' F	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Oct 2020 15:33:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Oct 2020 15:33:21
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 15:33:21
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:52:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'bpm'	System	21 Oct 2020 15:33:21
User entered empty.	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Oct 2020 15:33:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Oct 2020 15:33:21
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 15:33:21
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:52:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'breaths/min'	System	21 Oct 2020 15:33:21
User entered empty.	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Oct 2020 15:33:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Oct 2020 15:33:21
User entered '139' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 15:33:21
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:52:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'mmHg'	System	21 Oct 2020 15:33:21
User entered empty.	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Oct 2020 15:33:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Oct 2020 15:33:21
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 15:33:21
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:52:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:52:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'mmHg'	System	21 Oct 2020 15:33:21
User entered empty.	System	14 Aug 2020 13:52:42

US3672092

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:54:51

US3672092

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:54:51

US3672092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:39:35

US3672092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:39:35

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:39:35

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 15:39:35

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:39:35

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '11:35'	(b) (4), (b) (6)	13 Aug 2020 15:39:35

US3672092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '13 Aug 2020 11:35'	System	13 Aug 2020 15:39:35

US3672092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:39:35

US3672092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'ONCE'	System	13 Aug 2020 15:39:35

US3672092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 15:39:35

US3672092

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 13:57:43

US3672092

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 13:57:43

US3672092

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '11:10'	(b) (4), (b) (6)	14 Aug 2020 13:57:43

US3672092

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '13 Aug 2020 11:10'	System	14 Aug 2020 13:57:43

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:03:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:03:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:03:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '10:36'	(b) (4), (b) (6)	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '13 Aug 2020 10:36'	System	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:03:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:03:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	14 Aug 2020 13:58:27

US3672092

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 13:58:50

US3672092

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '1'	System	14 Aug 2020 13:58:50

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:05', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a6c0cfa8-2617-4daf-9041-b629189029b9'	System	13 Aug 2020 16:07:19
User entered 'Yes (Y)'	System	13 Aug 2020 16:07:19

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:10', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a6c0cfa8-2617-4daf-9041-b629189029b9'	System	13 Aug 2020 16:07:19
User entered '97.6'	System	13 Aug 2020 16:07:19

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:13', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a6c0cfa8-2617-4daf-9041-b629189029b9'	System	13 Aug 2020 16:07:19
User entered 'No (N)'	System	13 Aug 2020 16:07:19

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:18', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a6c0cfa8-2617-4daf-9041-b629189029b9'	System	13 Aug 2020 16:07:19
User entered '13 Aug 2020 12:07'	System	13 Aug 2020 16:07:19

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 11:55'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 14:25'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User closed query 'Please complete at home data.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 13:26:12
Query 'Please complete at home data.' answered with 'Subject missed entering Data on At Home Diary entry' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:37:48
User opened query 'Please complete at home data.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:31:54
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 15:20'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 2'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:03:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:04', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '765b9491-f424-4536-8181-e572fa5fb8ff'	System	15 Aug 2020 01:28:18
User entered 'Yes (Y)'	System	15 Aug 2020 01:28:18

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:03:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:10', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '765b9491-f424-4536-8181-e572fa5fb8ff'	System	15 Aug 2020 01:28:18
User entered '98.2'	System	15 Aug 2020 01:28:18

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:14', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '765b9491-f424-4536-8181-e572fa5fb8ff'	System	15 Aug 2020 01:28:18
User entered 'No (N)'	System	15 Aug 2020 01:28:18

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:17', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '765b9491-f424-4536-8181-e572fa5fb8ff'	System	15 Aug 2020 01:28:18
User entered '14 Aug 2020 21:28'	System	15 Aug 2020 01:28:18

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 3'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:03:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:04:54', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '85f1bab6-53ee-46f4-91bd-6d35e2d7c661'	System	15 Aug 2020 22:05:06
User entered 'Yes (Y)'	System	15 Aug 2020 22:05:06

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:03:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:04:59', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '85f1bab6-53ee-46f4-91bd-6d35e2d7c661'	System	15 Aug 2020 22:05:06
User entered '97.6'	System	15 Aug 2020 22:05:06

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:02', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '85f1bab6-53ee-46f4-91bd-6d35e2d7c661'	System	15 Aug 2020 22:05:06
User entered 'No (N)'	System	15 Aug 2020 22:05:06

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:05', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '85f1bab6-53ee-46f4-91bd-6d35e2d7c661'	System	15 Aug 2020 22:05:06
User entered '15 Aug 2020 18:05'	System	15 Aug 2020 22:05:06

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 4'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:03:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:09:57', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'aa840bc3-cf7a-4324-8613-97692f43c4e5'	System	16 Aug 2020 20:10:07
User entered 'Yes (Y)'	System	16 Aug 2020 20:10:07

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:03:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:02', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'aa840bc3-cf7a-4324-8613-97692f43c4e5'	System	16 Aug 2020 20:10:07
User entered '97.9'	System	16 Aug 2020 20:10:07

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:04', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'aa840bc3-cf7a-4324-8613-97692f43c4e5'	System	16 Aug 2020 20:10:07
User entered 'No (N)'	System	16 Aug 2020 20:10:07

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:07', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'aa840bc3-cf7a-4324-8613-97692f43c4e5'	System	16 Aug 2020 20:10:07
User entered '16 Aug 2020 16:10'	System	16 Aug 2020 20:10:07

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 5'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:03:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:21', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'dd82c8e3-c120-45df-bf30-093eb849ca53'	System	18 Aug 2020 00:42:32
User entered 'Yes (Y)'	System	18 Aug 2020 00:42:32

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:03:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:26', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'dd82c8e3-c120-45df-bf30-093eb849ca53'	System	18 Aug 2020 00:42:32
User entered '98.2'	System	18 Aug 2020 00:42:32

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:29', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'dd82c8e3-c120-45df-bf30-093eb849ca53'	System	18 Aug 2020 00:42:32
User entered 'No (N)'	System	18 Aug 2020 00:42:32

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:31', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'dd82c8e3-c120-45df-bf30-093eb849ca53'	System	18 Aug 2020 00:42:32
User entered '17 Aug 2020 20:42'	System	18 Aug 2020 00:42:32

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 6'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:03:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:05', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4717930a-845c-4ec4-8169-e19cbd419b3c'	System	19 Aug 2020 13:59:14
User entered 'Yes (Y)'	System	19 Aug 2020 13:59:14

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:03:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:09', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4717930a-845c-4ec4-8169-e19cbd419b3c'	System	19 Aug 2020 13:59:14
User entered '98.1'	System	19 Aug 2020 13:59:14

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:11', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4717930a-845c-4ec4-8169-e19cbd419b3c'	System	19 Aug 2020 13:59:14
User entered 'No (N)'	System	19 Aug 2020 13:59:14

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:14', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4717930a-845c-4ec4-8169-e19cbd419b3c'	System	19 Aug 2020 13:59:14
User entered '19 Aug 2020 09:59'	System	19 Aug 2020 13:59:14

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 7'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:03:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:25:46', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '3b73152b-3674-45f3-8f82-20c4eac87402'	System	19 Aug 2020 19:25:54
User entered 'Yes (Y)'	System	19 Aug 2020 19:25:54

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:03:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:25:50', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '3b73152b-3674-45f3-8f82-20c4eac87402'	System	19 Aug 2020 19:25:54
User entered '97.8'	System	19 Aug 2020 19:25:54

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:25:52', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '3b73152b-3674-45f3-8f82-20c4eac87402'	System	19 Aug 2020 19:25:54
User entered 'No (N)'	System	19 Aug 2020 19:25:54

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:25:54', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '3b73152b-3674-45f3-8f82-20c4eac87402'	System	19 Aug 2020 19:25:54
User entered '19 Aug 2020 15:25'	System	19 Aug 2020 19:25:54

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:29', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9094fcc1-3be9-4cd7-bbc6-ba1b4c9d735d'	System	13 Aug 2020 16:07:41
User entered 'None (1)'	System	13 Aug 2020 16:07:41

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:32', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9094fcc1-3be9-4cd7-bbc6-ba1b4c9d735d'	System	13 Aug 2020 16:07:41
User entered 'No (N)'	System	13 Aug 2020 16:07:41

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:34', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9094fcc1-3be9-4cd7-bbc6-ba1b4c9d735d'	System	13 Aug 2020 16:07:41
User entered 'No (N)'	System	13 Aug 2020 16:07:41

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:37', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9094fcc1-3be9-4cd7-bbc6-ba1b4c9d735d'	System	13 Aug 2020 16:07:41
User entered 'None (1)'	System	13 Aug 2020 16:07:41

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:39', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9094fcc1-3be9-4cd7-bbc6-ba1b4c9d735d'	System	13 Aug 2020 16:07:41
User entered '13 Aug 2020 12:07'	System	13 Aug 2020 16:07:41

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 11:55'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 14:25'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User closed query 'Please complete at home data.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 13:25:56
Query 'Please complete at home data.' answered with 'Subject missed entering data on At Home eDiary entry.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:38:38
User opened query 'Please complete at home data.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:32:56
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 15:20'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 2'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:32', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e94964a3-3b36-4990-925c-0dd9e907b58f'	System	15 Aug 2020 01:28:45
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 01:28:45

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:35', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e94964a3-3b36-4990-925c-0dd9e907b58f'	System	15 Aug 2020 01:28:45
User entered 'No (N)'	System	15 Aug 2020 01:28:45

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:37', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e94964a3-3b36-4990-925c-0dd9e907b58f'	System	15 Aug 2020 01:28:45
User entered 'No (N)'	System	15 Aug 2020 01:28:45

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:41', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e94964a3-3b36-4990-925c-0dd9e907b58f'	System	15 Aug 2020 01:28:45
User entered 'None (1)'	System	15 Aug 2020 01:28:45

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:44', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e94964a3-3b36-4990-925c-0dd9e907b58f'	System	15 Aug 2020 01:28:45
User entered '14 Aug 2020 21:28'	System	15 Aug 2020 01:28:45

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 3'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:14', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'f97accbb-b3dc-4eeb-a6a9-a7c7611b4bc2'	System	15 Aug 2020 22:05:30
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 22:05:30

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:17', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'f97accbb-b3dc-4eeb-a6a9-a7c7611b4bc2'	System	15 Aug 2020 22:05:30
User entered 'No (N)'	System	15 Aug 2020 22:05:30

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:22', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'f97accbb-b3dc-4eeb-a6a9-a7c7611b4bc2'	System	15 Aug 2020 22:05:30
User entered 'No (N)'	System	15 Aug 2020 22:05:30

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:25', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'f97accbb-b3dc-4eeb-a6a9-a7c7611b4bc2'	System	15 Aug 2020 22:05:30
User entered 'None (1)'	System	15 Aug 2020 22:05:30

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:29', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'f97accbb-b3dc-4eeb-a6a9-a7c7611b4bc2'	System	15 Aug 2020 22:05:30
User entered '15 Aug 2020 18:05'	System	15 Aug 2020 22:05:30

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 4'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:11', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '19f7fc4b-b18e-4ded-aa5d-c554e38700ba'	System	16 Aug 2020 20:10:23
User entered 'None (1)'	System	16 Aug 2020 20:10:23

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:13', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '19f7fc4b-b18e-4ded-aa5d-c554e38700ba'	System	16 Aug 2020 20:10:23
User entered 'No (N)'	System	16 Aug 2020 20:10:23

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:16', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '19f7fc4b-b18e-4ded-aa5d-c554e38700ba'	System	16 Aug 2020 20:10:23
User entered 'No (N)'	System	16 Aug 2020 20:10:23

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:19', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '19f7fc4b-b18e-4ded-aa5d-c554e38700ba'	System	16 Aug 2020 20:10:23
User entered 'None (1)'	System	16 Aug 2020 20:10:23

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:21', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '19f7fc4b-b18e-4ded-aa5d-c554e38700ba'	System	16 Aug 2020 20:10:23
User entered '16 Aug 2020 16:10'	System	16 Aug 2020 20:10:23

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 5'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:34', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2ec3cbc3-1637-47e3-813d-162d66d51edd'	System	18 Aug 2020 00:42:46
User entered 'None (1)'	System	18 Aug 2020 00:42:46

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:37', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2ec3cbc3-1637-47e3-813d-162d66d51edd'	System	18 Aug 2020 00:42:46
User entered 'No (N)'	System	18 Aug 2020 00:42:46

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:39', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2ec3cbc3-1637-47e3-813d-162d66d51edd'	System	18 Aug 2020 00:42:46
User entered 'No (N)'	System	18 Aug 2020 00:42:46

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:41', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2ec3cbc3-1637-47e3-813d-162d66d51edd'	System	18 Aug 2020 00:42:46
User entered 'None (1)'	System	18 Aug 2020 00:42:46

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:44', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2ec3cbc3-1637-47e3-813d-162d66d51edd'	System	18 Aug 2020 00:42:46
User entered '17 Aug 2020 20:42'	System	18 Aug 2020 00:42:46

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 6'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:17', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2cb396d4-80d9-4c97-bb30-0a5a1e913eb4'	System	19 Aug 2020 13:59:27
User entered 'None (1)'	System	19 Aug 2020 13:59:27

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:19', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2cb396d4-80d9-4c97-bb30-0a5a1e913eb4'	System	19 Aug 2020 13:59:27
User entered 'No (N)'	System	19 Aug 2020 13:59:27

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:21', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2cb396d4-80d9-4c97-bb30-0a5a1e913eb4'	System	19 Aug 2020 13:59:27
User entered 'No (N)'	System	19 Aug 2020 13:59:27

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:23', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2cb396d4-80d9-4c97-bb30-0a5a1e913eb4'	System	19 Aug 2020 13:59:27
User entered 'None (1)'	System	19 Aug 2020 13:59:27

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:25', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '2cb396d4-80d9-4c97-bb30-0a5a1e913eb4'	System	19 Aug 2020 13:59:27
User entered '19 Aug 2020 09:59'	System	19 Aug 2020 13:59:27

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 7'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:25:57', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '45f14095-7863-435d-b228-156f61ca5c42'	System	19 Aug 2020 19:26:08
User entered 'None (1)'	System	19 Aug 2020 19:26:08

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:25:59', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '45f14095-7863-435d-b228-156f61ca5c42'	System	19 Aug 2020 19:26:08
User entered 'No (N)'	System	19 Aug 2020 19:26:08

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:01', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '45f14095-7863-435d-b228-156f61ca5c42'	System	19 Aug 2020 19:26:08
User entered 'No (N)'	System	19 Aug 2020 19:26:08

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:05', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '45f14095-7863-435d-b228-156f61ca5c42'	System	19 Aug 2020 19:26:08
User entered 'None (1)'	System	19 Aug 2020 19:26:08

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:07', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '45f14095-7863-435d-b228-156f61ca5c42'	System	19 Aug 2020 19:26:08
User entered '19 Aug 2020 15:26'	System	19 Aug 2020 19:26:08

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:43', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a074e375-2508-42e7-8191-9023416e8242'	System	13 Aug 2020 16:08:08
User entered 'None (0)'	System	13 Aug 2020 16:08:08

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:46', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a074e375-2508-42e7-8191-9023416e8242'	System	13 Aug 2020 16:08:08
User entered 'None (0)'	System	13 Aug 2020 16:08:08

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:48', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a074e375-2508-42e7-8191-9023416e8242'	System	13 Aug 2020 16:08:08
User entered 'None (0)'	System	13 Aug 2020 16:08:08

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:51', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a074e375-2508-42e7-8191-9023416e8242'	System	13 Aug 2020 16:08:08
User entered 'None (0)'	System	13 Aug 2020 16:08:08

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:53', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a074e375-2508-42e7-8191-9023416e8242'	System	13 Aug 2020 16:08:08
User entered 'None (0)'	System	13 Aug 2020 16:08:08

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:07:56', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a074e375-2508-42e7-8191-9023416e8242'	System	13 Aug 2020 16:08:08
User entered 'None (0)'	System	13 Aug 2020 16:08:08

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:08:02', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a074e375-2508-42e7-8191-9023416e8242'	System	13 Aug 2020 16:08:08
User entered 'No (N)'	System	13 Aug 2020 16:08:08

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-13T12:08:06', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a074e375-2508-42e7-8191-9023416e8242'	System	13 Aug 2020 16:08:08
User entered '13 Aug 2020 12:08'	System	13 Aug 2020 16:08:08

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 11:55'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 14:25'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User closed query 'Please complete at home data.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 13:25:48
Query 'Please complete at home data.' answered with 'subject missed diary entry' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 20:34:58
User opened query 'Please complete at home data.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 15:34:01
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '13 Aug 2020 15:20'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 2'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:48', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '6811f448-afb0-41ba-9be3-1f6d10ca72db'	System	15 Aug 2020 01:29:13
User entered 'None (0)'	System	15 Aug 2020 01:29:13

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:54', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '6811f448-afb0-41ba-9be3-1f6d10ca72db'	System	15 Aug 2020 01:29:13
User entered 'No interference with activity (1)'	System	15 Aug 2020 01:29:13

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:28:57', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '6811f448-afb0-41ba-9be3-1f6d10ca72db'	System	15 Aug 2020 01:29:13
User entered 'No interference with activity (1)'	System	15 Aug 2020 01:29:13

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:29:02', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '6811f448-afb0-41ba-9be3-1f6d10ca72db'	System	15 Aug 2020 01:29:13
User entered 'No interference with activity (1)'	System	15 Aug 2020 01:29:13

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:29:04', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '6811f448-afb0-41ba-9be3-1f6d10ca72db'	System	15 Aug 2020 01:29:13
User entered 'None (0)'	System	15 Aug 2020 01:29:13

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:29:06', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '6811f448-afb0-41ba-9be3-1f6d10ca72db'	System	15 Aug 2020 01:29:13
User entered 'None (0)'	System	15 Aug 2020 01:29:13

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:29:09', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '6811f448-afb0-41ba-9be3-1f6d10ca72db'	System	15 Aug 2020 01:29:13
User entered 'No (N)'	System	15 Aug 2020 01:29:13

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-14T21:29:11', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '6811f448-afb0-41ba-9be3-1f6d10ca72db'	System	15 Aug 2020 01:29:13
User entered '14 Aug 2020 21:29'	System	15 Aug 2020 01:29:13

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 3'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:33', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5ef56b21-21ae-42d9-94dd-71cfbfbf1711'	System	15 Aug 2020 22:05:54
User entered 'None (0)'	System	15 Aug 2020 22:05:54

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:37', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5ef56b21-21ae-42d9-94dd-71cfbfbf1711'	System	15 Aug 2020 22:05:54
User entered 'None (0)'	System	15 Aug 2020 22:05:54

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:40', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5ef56b21-21ae-42d9-94dd-71cfbfbf1711'	System	15 Aug 2020 22:05:54
User entered 'None (0)'	System	15 Aug 2020 22:05:54

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:42', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5ef56b21-21ae-42d9-94dd-71cfbfbf1711'	System	15 Aug 2020 22:05:54
User entered 'None (0)'	System	15 Aug 2020 22:05:54

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:43', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5ef56b21-21ae-42d9-94dd-71cfbfbf1711'	System	15 Aug 2020 22:05:54
User entered 'None (0)'	System	15 Aug 2020 22:05:54

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:46', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5ef56b21-21ae-42d9-94dd-71cfbfbf1711'	System	15 Aug 2020 22:05:54
User entered 'None (0)'	System	15 Aug 2020 22:05:54

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:50', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5ef56b21-21ae-42d9-94dd-71cfbfbf1711'	System	15 Aug 2020 22:05:54
User entered 'No (N)'	System	15 Aug 2020 22:05:54

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-15T18:05:52', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5ef56b21-21ae-42d9-94dd-71cfbfbf1711'	System	15 Aug 2020 22:05:54
User entered '15 Aug 2020 18:05'	System	15 Aug 2020 22:05:54

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 4'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:26', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'd5e9f736-85b0-42f4-a69e-da87a0f2daef'	System	16 Aug 2020 20:10:43
User entered 'None (0)'	System	16 Aug 2020 20:10:43

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:28', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'd5e9f736-85b0-42f4-a69e-da87a0f2daef'	System	16 Aug 2020 20:10:43
User entered 'None (0)'	System	16 Aug 2020 20:10:43

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:30', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'd5e9f736-85b0-42f4-a69e-da87a0f2daef'	System	16 Aug 2020 20:10:43
User entered 'None (0)'	System	16 Aug 2020 20:10:43

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:32', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'd5e9f736-85b0-42f4-a69e-da87a0f2daef'	System	16 Aug 2020 20:10:43
User entered 'None (0)'	System	16 Aug 2020 20:10:43

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:34', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'd5e9f736-85b0-42f4-a69e-da87a0f2daef'	System	16 Aug 2020 20:10:43
User entered 'None (0)'	System	16 Aug 2020 20:10:43

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:36', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'd5e9f736-85b0-42f4-a69e-da87a0f2daef'	System	16 Aug 2020 20:10:43
User entered 'None (0)'	System	16 Aug 2020 20:10:43

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:40', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'd5e9f736-85b0-42f4-a69e-da87a0f2daef'	System	16 Aug 2020 20:10:43
User entered 'No (N)'	System	16 Aug 2020 20:10:43

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-16T16:10:43', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'd5e9f736-85b0-42f4-a69e-da87a0f2daef'	System	16 Aug 2020 20:10:43
User entered '16 Aug 2020 16:10'	System	16 Aug 2020 20:10:43

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 5'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:47', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c018c020-1938-4cb2-874e-637584684c8e'	System	18 Aug 2020 00:43:03
User entered 'None (0)'	System	18 Aug 2020 00:43:03

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:49', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c018c020-1938-4cb2-874e-637584684c8e'	System	18 Aug 2020 00:43:03
User entered 'None (0)'	System	18 Aug 2020 00:43:03

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:52', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c018c020-1938-4cb2-874e-637584684c8e'	System	18 Aug 2020 00:43:03
User entered 'None (0)'	System	18 Aug 2020 00:43:03

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:54', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c018c020-1938-4cb2-874e-637584684c8e'	System	18 Aug 2020 00:43:03
User entered 'None (0)'	System	18 Aug 2020 00:43:03

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:56', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c018c020-1938-4cb2-874e-637584684c8e'	System	18 Aug 2020 00:43:03
User entered 'None (0)'	System	18 Aug 2020 00:43:03

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:42:59', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c018c020-1938-4cb2-874e-637584684c8e'	System	18 Aug 2020 00:43:03
User entered 'None (0)'	System	18 Aug 2020 00:43:03

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:43:02', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c018c020-1938-4cb2-874e-637584684c8e'	System	18 Aug 2020 00:43:03
User entered 'No (N)'	System	18 Aug 2020 00:43:03

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-17T20:43:03', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c018c020-1938-4cb2-874e-637584684c8e'	System	18 Aug 2020 00:43:03
User entered '17 Aug 2020 20:43'	System	18 Aug 2020 00:43:03

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 6'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:28', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c828517b-610d-43ec-8018-3e70e9c73716'	System	19 Aug 2020 13:59:44
User entered 'None (0)'	System	19 Aug 2020 13:59:44

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:30', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c828517b-610d-43ec-8018-3e70e9c73716'	System	19 Aug 2020 13:59:44
User entered 'None (0)'	System	19 Aug 2020 13:59:44

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:32', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c828517b-610d-43ec-8018-3e70e9c73716'	System	19 Aug 2020 13:59:44
User entered 'None (0)'	System	19 Aug 2020 13:59:44

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:33', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c828517b-610d-43ec-8018-3e70e9c73716'	System	19 Aug 2020 13:59:44
User entered 'None (0)'	System	19 Aug 2020 13:59:44

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:36', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c828517b-610d-43ec-8018-3e70e9c73716'	System	19 Aug 2020 13:59:44
User entered 'None (0)'	System	19 Aug 2020 13:59:44

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:38', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c828517b-610d-43ec-8018-3e70e9c73716'	System	19 Aug 2020 13:59:44
User entered 'None (0)'	System	19 Aug 2020 13:59:44

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:40', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c828517b-610d-43ec-8018-3e70e9c73716'	System	19 Aug 2020 13:59:44
User entered 'No (N)'	System	19 Aug 2020 13:59:44

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T09:59:44', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c828517b-610d-43ec-8018-3e70e9c73716'	System	19 Aug 2020 13:59:44
User entered '19 Aug 2020 09:59'	System	19 Aug 2020 13:59:44

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 7'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:11', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '62963580-4cc3-4645-b1c6-5e03cb078041'	System	19 Aug 2020 19:26:25
User entered 'None (0)'	System	19 Aug 2020 19:26:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:13', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '62963580-4cc3-4645-b1c6-5e03cb078041'	System	19 Aug 2020 19:26:25
User entered 'None (0)'	System	19 Aug 2020 19:26:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:15', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '62963580-4cc3-4645-b1c6-5e03cb078041'	System	19 Aug 2020 19:26:25
User entered 'None (0)'	System	19 Aug 2020 19:26:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:17', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '62963580-4cc3-4645-b1c6-5e03cb078041'	System	19 Aug 2020 19:26:25
User entered 'None (0)'	System	19 Aug 2020 19:26:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:19', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '62963580-4cc3-4645-b1c6-5e03cb078041'	System	19 Aug 2020 19:26:25
User entered 'None (0)'	System	19 Aug 2020 19:26:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:21', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '62963580-4cc3-4645-b1c6-5e03cb078041'	System	19 Aug 2020 19:26:25
User entered 'None (0)'	System	19 Aug 2020 19:26:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:23', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '62963580-4cc3-4645-b1c6-5e03cb078041'	System	19 Aug 2020 19:26:25
User entered 'No (N)'	System	19 Aug 2020 19:26:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-08-19T15:26:25', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '62963580-4cc3-4645-b1c6-5e03cb078041'	System	19 Aug 2020 19:26:25
User entered '19 Aug 2020 15:26'	System	19 Aug 2020 19:26:25

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:39:35

US3672092

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:03:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:42:17

US3672092

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 19:42:17

US3672092

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Aug 2020 19:42:17

US3672092

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:42:17

US3672092

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:42:20

US3672092

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'I'	System	20 Aug 2020 19:42:20

US3672092

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 13:41:30

US3672092

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 13:41:30

US3672092

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Sep 2020 13:41:30

US3672092

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:41:30

US3672092

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 13:41:36

US3672092

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'I'	System	01 Sep 2020 13:41:36

US3672092

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:57:01

US3672092

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 20:57:01

US3672092

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Sep 2020 20:57:01

US3672092

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:57:01

US3672092

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:57:05

US3672092

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'I'	System	03 Sep 2020 20:57:05

US3672092

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:02:06

US3672092

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	11 Sep 2020 05:41:08
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'DATE IS CONFIRMED. ' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 18:02:35
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	10 Sep 2020 18:02:06
User entered '09 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 18:02:06

US3672092

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:02:06

US3672092

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'VISIT2'	System	10 Sep 2020 18:02:06

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:03:49
User entered '09 Sep 2020' reason for change: Data Entry Error	System	10 Sep 2020 18:03:49
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 18:02:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:03:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:03:49
User entered '17:01' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:03:49
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:02:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '09 Sep 2020 17:01'	System	10 Sep 2020 18:03:49
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:03:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:03:49
User entered '98.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:03:49
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:02:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:03:49
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:03:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:03:49
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:03:49
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:02:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'bpm'	System	10 Sep 2020 18:03:49
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:03:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:03:49
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:03:49
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:02:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'breaths/min'	System	10 Sep 2020 18:03:49
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:03:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:03:49
User entered '127' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:03:49
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:02:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'mmHg'	System	10 Sep 2020 18:03:49
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:03:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:03:49
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:03:49
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:02:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'mmHg'	System	10 Sep 2020 18:03:49
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:03:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:02:57

US3672092

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:04:15

US3672092

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:04:15

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User closed query 'Per CDM: The reason provided on Dosing discontinuation page 'SWELLING AT INJECTION SITE' that does not match with reason 'PATIENT IS BEING TREATED WITH PREDNISONE' Please confirm the correct reason of Dosing discontinuation and update it appropriately or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:19:44
Query 'Per CDM: The reason provided on Dosing discontinuation page 'SWELLING AT INJECTION SITE' that does not match with reason 'PATIENT IS BEING TREATED WITH PREDNISONE' Please confirm the correct reason of Dosing discontinuation and update it appropriately or else clarify. Thank you.' answered with 'confirmed that swelling at injection site was reason of no 2nd vax.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:56:43
User entered 'SWELLING AT INJECTION SITE' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:56:23
User opened query 'Per CDM: The reason provided on Dosing discontinuation page 'SWELLING AT INJECTION SITE' that does not match with reason 'PATIENT IS BEING TREATED WITH PREDNISONE' Please confirm the correct reason of Dosing discontinuation and update it appropriately or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 04:33:32
User entered 'PATIENT IS BEING TREATED WITH PREDNISONE'	(b) (4), (b) (6)	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:03:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:18:14

US3672092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:13:06

US3672092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:13:06

US3672092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '17:29'	(b) (4), (b) (6)	10 Sep 2020 18:13:06

US3672092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '09 Sep 2020 17:29'	System	10 Sep 2020 18:13:06

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:03:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '09 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:03:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:03:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '17:29'	(b) (4), (b) (6)	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '09 Sep 2020 17:29'	System	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:03:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
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	10 Sep 2020 18:16:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:16:46
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:16:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:03:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered empty.	System	10 Sep 2020 18:16:36

US3672092

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:16:51

US3672092

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '1'	System	10 Sep 2020 18:16:51

US3672092

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 18:41:44

US3672092

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 18:41:44

US3672092

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 18:41:44

US3672092

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:41:44

US3672092

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 18:41:48

US3672092

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '1'	System	16 Sep 2020 18:41:48

US3672092

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:53:17

US3672092

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:53:17

US3672092

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 19:53:17

US3672092

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:53:17

US3672092

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:53:20

US3672092

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'I'	System	23 Sep 2020 19:53:20

US3672092

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 17:43:38

US3672092

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:43:38

US3672092

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:43:38

US3672092

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:43:38

US3672092

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:48:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:45:32

US3672092

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '1'	System	30 Sep 2020 17:45:32

US3672092

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:08:49

US3672092

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:08:49

US3672092

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:08:49

US3672092

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'VISIT3'	System	09 Oct 2020 17:08:49

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '10:04'	(b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '8 Oct 2020 10:04'	System	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '97.9' F	(b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '61'	(b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'bpm'	System	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '15'	(b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'breaths/min'	System	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '125'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'mmHg'	System	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '71'	(b) (4), (b) (6)	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'mmHg'	System	09 Oct 2020 17:09:20

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14

US3672092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:03:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14

US3672092

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:09:33

US3672092

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:03:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:09:33

US3672092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:09:48

US3672092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:09:48

US3672092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered '10:18'	(b) (4), (b) (6)	09 Oct 2020 17:09:48

US3672092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered '8 Oct 2020 10:18'	System	09 Oct 2020 17:09:48

US3672092

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:49:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:09:57

US3672092

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'I'	System	09 Oct 2020 17:09:57

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 64'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-16T10:28:10', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '78a68934-5acf-4901-af84-b57e75fb9e4f'	System	16 Oct 2020 14:28:19
User entered 'No (N)'	System	16 Oct 2020 14:28:19

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-16T10:28:13', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '78a68934-5acf-4901-af84-b57e75fb9e4f'	System	16 Oct 2020 14:28:19
User entered 'No (N)'	System	16 Oct 2020 14:28:19

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-16T10:28:17', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '78a68934-5acf-4901-af84-b57e75fb9e4f' User entered '16 Oct 2020 10:28:17'	System	16 Oct 2020 14:28:19
	System	16 Oct 2020 14:28:19

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 71'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-23T13:01:51', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '915e1116-ca81-4c69-ab08-8351227e5e9d'	System	23 Oct 2020 17:02:07
User entered 'No (N)'	System	23 Oct 2020 17:02:07

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-23T13:01:54', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '915e1116-ca81-4c69-ab08-8351227e5e9d'	System	23 Oct 2020 17:02:07
User entered 'No (N)'	System	23 Oct 2020 17:02:07

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-23T13:01:58', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '915e1116-ca81-4c69-ab08-8351227e5e9d' User entered '23 Oct 2020 13:01:58'	System	23 Oct 2020 17:02:07
	System	23 Oct 2020 17:02:07

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 78'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-30T09:41:18', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '151dfb3b-1fbb-4e27-94c1-e058783d94f6'	System	30 Oct 2020 13:41:24
User entered 'No (N)'	System	30 Oct 2020 13:41:24

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-30T09:41:21', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '151dfb3b-1fbb-4e27-94c1-e058783d94f6'	System	30 Oct 2020 13:41:24
User entered 'No (N)'	System	30 Oct 2020 13:41:24

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-10-30T09:41:24', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '151dfb3b-1fbb-4e27-94c1-e058783d94f6'	System	30 Oct 2020 13:41:24
User entered '30 Oct 2020 09:41:24'	System	30 Oct 2020 13:41:24

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 92'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-11-10T17:26:26', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '278c9ea7-4b24-459d-87c6-ee82bd1fd93f'	System	10 Nov 2020 22:26:38
User entered 'No (N)'	System	10 Nov 2020 22:26:38

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-11-10T17:26:32', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '278c9ea7-4b24-459d-87c6-ee82bd1fd93f'	System	10 Nov 2020 22:26:38
User entered 'No (N)'	System	10 Nov 2020 22:26:38

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-11-10T17:26:35', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '278c9ea7-4b24-459d-87c6-ee82bd1fd93f'	System	10 Nov 2020 22:26:38
User entered '10 Nov 2020 17:26:35'	System	10 Nov 2020 22:26:38

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered 'Day 99'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-11-17T13:47:56', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '07d3ed47-3f8f-4833-8a8a-7155e9debafc'	System	17 Nov 2020 18:48:09
User entered 'No (N)'	System	17 Nov 2020 18:48:09

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-11-17T13:48:01', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '07d3ed47-3f8f-4833-8a8a-7155e9debafc'	System	17 Nov 2020 18:48:09
User entered 'No (N)'	System	17 Nov 2020 18:48:09

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-11-17T13:48:05', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '07d3ed47-3f8f-4833-8a8a-7155e9debafc'	System	17 Nov 2020 18:48:09
User entered '17 Nov 2020 13:48:05'	System	17 Nov 2020 18:48:09

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 15:39:35

US3672092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:15:53
Data entry locked.	System	13 Aug 2020 15:39:35
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 15:39:35

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2020-11-22T17:50:05', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c55ecb2f-7993-41dc-b421-28f02c520eaa'	System	22 Nov 2020 22:51:13
User entered 'No (N)'	System	22 Nov 2020 22:51:13

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2020-11-22T17:51:07', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c55ecb2f-7993-41dc-b421-28f02c520eaa'	System	22 Nov 2020 22:51:13
User entered 'No (N)'	System	22 Nov 2020 22:51:13

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-11-22T17:51:09', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'c55ecb2f-7993-41dc-b421-28f02c520eaa'	System	22 Nov 2020 22:51:13
User entered '22 Nov 2020 17:51:09'	System	22 Nov 2020 22:51:13

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2020-11-28T10:51:31', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4cd2eb9e-803b-45a6-b34e-ad19495c8a1c'	System	28 Nov 2020 15:51:37
User entered 'No (N)'	System	28 Nov 2020 15:51:37

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2020-11-28T10:51:34', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4cd2eb9e-803b-45a6-b34e-ad19495c8a1c'	System	28 Nov 2020 15:51:37
User entered 'No (N)'	System	28 Nov 2020 15:51:37

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-11-28T10:51:37', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4cd2eb9e-803b-45a6-b34e-ad19495c8a1c'	System	28 Nov 2020 15:51:37
User entered '28 Nov 2020 10:51:37'	System	28 Nov 2020 15:51:37

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2020-12-06T15:16:51', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '57000d9f-43c0-44a1-90f6-b6e63ab6b491'	System	06 Dec 2020 20:16:59
User entered 'No (N)'	System	06 Dec 2020 20:16:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2020-12-06T15:16:53', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '57000d9f-43c0-44a1-90f6-b6e63ab6b491'	System	06 Dec 2020 20:16:59
User entered 'No (N)'	System	06 Dec 2020 20:16:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-12-06T15:16:55', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '57000d9f-43c0-44a1-90f6-b6e63ab6b491'	System	06 Dec 2020 20:16:59
User entered '06 Dec 2020 15:16:55'	System	06 Dec 2020 20:16:59

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2020-12-12T11:05:20', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9efe195b-4462-44c9-912e-c25c4ad6facb'	System	12 Dec 2020 16:05:27
User entered 'No (N)'	System	12 Dec 2020 16:05:27

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2020-12-12T11:05:23', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9efe195b-4462-44c9-912e-c25c4ad6facb'	System	12 Dec 2020 16:05:27
User entered 'No (N)'	System	12 Dec 2020 16:05:27

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-12-12T11:05:24', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9efe195b-4462-44c9-912e-c25c4ad6facb'	System	12 Dec 2020 16:05:27
User entered '12 Dec 2020 11:05:24'	System	12 Dec 2020 16:05:27

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2020-12-19T13:28:15', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'cd72a8b7-5d8c-48cb-a3a4-179d3a851d6c'	System	19 Dec 2020 18:28:24
User entered 'No (N)'	System	19 Dec 2020 18:28:24

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2020-12-19T13:28:19', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'cd72a8b7-5d8c-48cb-a3a4-179d3a851d6c'	System	19 Dec 2020 18:28:24
User entered 'No (N)'	System	19 Dec 2020 18:28:24

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-12-19T13:28:22', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'cd72a8b7-5d8c-48cb-a3a4-179d3a851d6c'	System	19 Dec 2020 18:28:24
User entered '19 Dec 2020 13:28:22'	System	19 Dec 2020 18:28:24

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2020-12-26T11:11:42', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4a9374fa-01f8-4d44-ab95-a56205842691'	System	26 Dec 2020 16:11:48
User entered 'No (N)'	System	26 Dec 2020 16:11:48

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2020-12-26T11:11:44', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4a9374fa-01f8-4d44-ab95-a56205842691'	System	26 Dec 2020 16:11:48
User entered 'No (N)'	System	26 Dec 2020 16:11:48

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2020-12-26T11:11:46', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4a9374fa-01f8-4d44-ab95-a56205842691'	System	26 Dec 2020 16:11:48
User entered '26 Dec 2020 11:11:46'	System	26 Dec 2020 16:11:48

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-01-02T11:18:40', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e446c2eb-2923-48a8-91e6-07a426ef8530'	System	02 Jan 2021 16:18:45
User entered 'No (N)'	System	02 Jan 2021 16:18:45

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-01-02T11:18:41', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e446c2eb-2923-48a8-91e6-07a426ef8530'	System	02 Jan 2021 16:18:45
User entered 'No (N)'	System	02 Jan 2021 16:18:45

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-01-02T11:18:43', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e446c2eb-2923-48a8-91e6-07a426ef8530'	System	02 Jan 2021 16:18:45
User entered '02 Jan 2021 11:18:43'	System	02 Jan 2021 16:18:45

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-01-16T13:53:08', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9a49be46-38f4-4651-bddb-7ac43b8fc3c0'	System	16 Jan 2021 18:53:19
User entered 'No (N)'	System	16 Jan 2021 18:53:19

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-01-16T13:53:10', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9a49be46-38f4-4651-bddb-7ac43b8fc3c0'	System	16 Jan 2021 18:53:19
User entered 'No (N)'	System	16 Jan 2021 18:53:19

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-01-16T13:53:12', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '9a49be46-38f4-4651-bddb-7ac43b8fc3c0'	System	16 Jan 2021 18:53:19
User entered '16 Jan 2021 13:53:12'	System	16 Jan 2021 18:53:19

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-01-24T09:41:08', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e7eec7cc-06c7-4199-92bb-d4ccb34b2c96'	System	24 Jan 2021 14:41:14
User entered 'No (N)'	System	24 Jan 2021 14:41:14

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-01-24T09:41:11', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e7eec7cc-06c7-4199-92bb-d4ccb34b2c96'	System	24 Jan 2021 14:41:14
User entered 'No (N)'	System	24 Jan 2021 14:41:14

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-01-24T09:41:13', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'e7eec7cc-06c7-4199-92bb-d4ccb34b2c96'	System	24 Jan 2021 14:41:14
User entered '24 Jan 2021 09:41:13'	System	24 Jan 2021 14:41:14

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-01-30T09:19:19', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'eb3ec400-8846-48ec-8767-f363f8dee08d'	System	30 Jan 2021 14:19:24
User entered 'No (N)'	System	30 Jan 2021 14:19:24

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-01-30T09:19:22', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'eb3ec400-8846-48ec-8767-f363f8dee08d'	System	30 Jan 2021 14:19:24
User entered 'No (N)'	System	30 Jan 2021 14:19:24

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-01-30T09:19:24', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'eb3ec400-8846-48ec-8767-f363f8dee08d'	System	30 Jan 2021 14:19:24
User entered '30 Jan 2021 09:19:24'	System	30 Jan 2021 14:19:24

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-02-07T11:26:07', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a7b66863-648f-4d9f-8d93-7442d9f876fd'	System	07 Feb 2021 16:26:10
User entered 'No (N)'	System	07 Feb 2021 16:26:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-02-07T11:26:09', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a7b66863-648f-4d9f-8d93-7442d9f876fd'	System	07 Feb 2021 16:26:10
User entered 'No (N)'	System	07 Feb 2021 16:26:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-02-07T11:26:11', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'a7b66863-648f-4d9f-8d93-7442d9f876fd'	System	07 Feb 2021 16:26:10
User entered '07 Feb 2021 11:26:11'	System	07 Feb 2021 16:26:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-02-13T11:23:11', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '462b4678-d84a-4ab9-b189-3e73a1166799'	System	13 Feb 2021 16:23:19
User entered 'No (N)'	System	13 Feb 2021 16:23:19

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-02-13T11:23:13', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '462b4678-d84a-4ab9-b189-3e73a1166799'	System	13 Feb 2021 16:23:19
User entered 'No (N)'	System	13 Feb 2021 16:23:19

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-02-13T11:23:15', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '462b4678-d84a-4ab9-b189-3e73a1166799'	System	13 Feb 2021 16:23:19
User entered '13 Feb 2021 11:23:15'	System	13 Feb 2021 16:23:19

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-02-20T12:45:44', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '51515e27-c21c-455f-a1bb-596df71b38f9'	System	20 Feb 2021 17:45:51
User entered 'No (N)'	System	20 Feb 2021 17:45:51

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-02-20T12:45:46', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '51515e27-c21c-455f-a1bb-596df71b38f9'	System	20 Feb 2021 17:45:51
User entered 'No (N)'	System	20 Feb 2021 17:45:51

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-02-20T12:45:48', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '51515e27-c21c-455f-a1bb-596df71b38f9'	System	20 Feb 2021 17:45:51
User entered '20 Feb 2021 12:45:48'	System	20 Feb 2021 17:45:51

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-02-27T18:26:07-05:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'df8c2690-3bb4-4d00-967f-98d9f931b060'	System	27 Feb 2021 23:26:12
User entered 'No (N)'	System	27 Feb 2021 23:26:12

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-02-27T18:26:08-05:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'df8c2690-3bb4-4d00-967f-98d9f931b060'	System	27 Feb 2021 23:26:12
User entered 'No (N)'	System	27 Feb 2021 23:26:12

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-02-27T18:26:10-05:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'df8c2690-3bb4-4d00-967f-98d9f931b060'	System	27 Feb 2021 23:26:12
User entered '27 Feb 2021 18:26:10'	System	27 Feb 2021 23:26:12

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-03-07T13:38:06-05:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '191a3612-a270-4eb5-9b6c-6ad55b82095b'	System	07 Mar 2021 18:38:14
User entered 'No (N)'	System	07 Mar 2021 18:38:14

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-03-07T13:38:09-05:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '191a3612-a270-4eb5-9b6c-6ad55b82095b'	System	07 Mar 2021 18:38:14
User entered 'No (N)'	System	07 Mar 2021 18:38:14

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-03-07T13:38:11-05:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '191a3612-a270-4eb5-9b6c-6ad55b82095b' User entered '07 Mar 2021 13:38:11'	System	07 Mar 2021 18:38:14
	System	07 Mar 2021 18:38:14

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-03-15T09:24:59-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '91c52ba8-1cac-4ab9-8e0b-44c23bbddfc6'	System	15 Mar 2021 13:25:08
User entered 'No (N)'	System	15 Mar 2021 13:25:08

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-03-15T09:25:01-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '91c52ba8-1cac-4ab9-8e0b-44c23bbddfc6'	System	15 Mar 2021 13:25:08
User entered 'No (N)'	System	15 Mar 2021 13:25:08

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-03-15T09:25:04-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '91c52ba8-1cac-4ab9-8e0b-44c23bbddfc6'	System	15 Mar 2021 13:25:08
User entered '15 Mar 2021 09:25:04'	System	15 Mar 2021 13:25:08

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-03-21T12:24:32-06:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '044d5d70-ecab-48aa-9eeb-5954a153b05a' User entered 'No (N)'	System	21 Mar 2021 18:24:39
	System	21 Mar 2021 18:24:39

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-03-21T12:24:34-06:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '044d5d70-ecab-48aa-9eeb-5954a153b05a'	System	21 Mar 2021 18:24:39
User entered 'No (N)'	System	21 Mar 2021 18:24:39

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-03-21T12:24:36-06:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '044d5d70-ecab-48aa-9eeb-5954a153b05a'	System	21 Mar 2021 18:24:39
User entered '21 Mar 2021 12:24:36'	System	21 Mar 2021 18:24:39

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-04-04T10:53:47-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '699f3586-a1f6-4532-bebd-84608c156225'	System	04 Apr 2021 14:53:51
User entered 'No (N)'	System	04 Apr 2021 14:53:51

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-04-04T10:53:48-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '699f3586-a1f6-4532-bebd-84608c156225'	System	04 Apr 2021 14:53:51
User entered 'No (N)'	System	04 Apr 2021 14:53:51

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-04-04T10:53:50-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '699f3586-a1f6-4532-bebd-84608c156225'	System	04 Apr 2021 14:53:51
User entered '04 Apr 2021 10:53:50'	System	04 Apr 2021 14:53:51

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-04-11T15:35:25-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5fbf19d9-3a27-430b-89db-1f7c2327b830'	System	11 Apr 2021 19:35:28
User entered 'No (N)'	System	11 Apr 2021 19:35:28

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-04-11T15:35:27-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5fbf19d9-3a27-430b-89db-1f7c2327b830'	System	11 Apr 2021 19:35:28
User entered 'No (N)'	System	11 Apr 2021 19:35:28

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-04-11T15:35:28-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '5fbf19d9-3a27-430b-89db-1f7c2327b830'	System	11 Apr 2021 19:35:28
User entered '11 Apr 2021 15:35:28'	System	11 Apr 2021 19:35:28

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-04-18T06:05:49-07:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'b5d08e90-0e1f-49e8-ac04-ae75a3cc8c49'	System	18 Apr 2021 13:05:56
User entered 'No (N)'	System	18 Apr 2021 13:05:56

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-04-18T06:05:50-07:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'b5d08e90-0e1f-49e8-ac04-ae75a3cc8c49'	System	18 Apr 2021 13:05:56
User entered 'No (N)'	System	18 Apr 2021 13:05:56

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-04-18T06:05:52-07:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'b5d08e90-0e1f-49e8-ac04-ae75a3cc8c49'	System	18 Apr 2021 13:05:56
User entered '18 Apr 2021 06:05:52'	System	18 Apr 2021 13:05:56

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-04-25T09:46:55-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4bcc9422-3555-4484-aabe-12f12dfaef93'	System	25 Apr 2021 13:47:06
User entered 'No (N)'	System	25 Apr 2021 13:47:06

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-04-25T09:46:58-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4bcc9422-3555-4484-aabe-12f12dfaef93'	System	25 Apr 2021 13:47:06
User entered 'No (N)'	System	25 Apr 2021 13:47:06

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-04-25T09:47:00-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4bcc9422-3555-4484-aabe-12f12dfaef93'	System	25 Apr 2021 13:47:06
User entered '25 Apr 2021 09:47:00'	System	25 Apr 2021 13:47:06

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[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 (5528d1c3118e9512)', Time: '2021-05-01T15:39:33-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4a02c040-3e83-4fbc-b806-19e719e82b1c' User entered 'No (N)'	System	01 May 2021 19:39:43
	System	01 May 2021 19:39:43

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

Have you been exposed to someone with 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 (5528d1c3118e9512)', Time: '2021-05-01T15:39:35-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4a02c040-3e83-4fbc-b806-19e719e82b1c'	System	01 May 2021 19:39:43
User entered 'No (N)'	System	01 May 2021 19:39:43

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-05-01T15:39:37-04:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: '4a02c040-3e83-4fbc-b806-19e719e82b1c' User entered '01 May 2021 15:39:37'	System	01 May 2021 19:39:43
	System	01 May 2021 19:39:43

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 05:56:10

US3672092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:03:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:56:10
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 05:56:10

US3672092

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:03:53

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 02:21:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-02-27T18:26:16-05:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'de7eb168-d59c-46d5-9ee9-9b9c58762b7e'	System	27 Feb 2021 23:26:18
User entered 'No (N)'	System	27 Feb 2021 23:26:18

US3672092

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:03:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:21:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5528d1c3118e9512)', Time: '2021-02-27T18:26:19-05:00', User OID: 'PatientReportedOutcome (US3672092)', ODM File OID: 'de7eb168-d59c-46d5-9ee9-9b9c58762b7e' User entered '27 Feb 2021 18:26:19'	System	27 Feb 2021 23:26:18
	System	27 Feb 2021 23:26:18

US3672092

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:44:34

US3672092

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 21:44:34

US3672092

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 21:44:34

US3672092

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:34

US3672092

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:44:40

US3672092

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:50:14
User entered 'I'	System	05 Nov 2020 21:44:40

US3672092

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 18:54:11

US3672092

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '24 Nov 2020'	(b) (4), (b) (6)	11 Jan 2021 18:54:11

US3672092

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 18:54:11

US3672092

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 18:54:11

US3672092

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 18:54:18

US3672092

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User entered '1'	System	11 Jan 2021 18:54:18

US3672092

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 18:54:44

US3672092

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 18:54:44

US3672092

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 18:54:44

US3672092

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 18:54:44

US3672092

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 18:54:51

US3672092

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User entered 'I'	System	11 Jan 2021 18:54:51

US3672092

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:20:37

US3672092

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:20:37

US3672092

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:20:37

US3672092

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:03:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:20:37

US3672092

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:20:41

US3672092

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:03:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:05:33
User entered '1'	System	15 Feb 2021 17:20:41

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

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 14:47:59

US3672092

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

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:47:59

US3672092

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

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[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 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:47:59

US3672092

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

Form: Visit Date

Generated On: 11 Aug 2021 23:03:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 14:47:59

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:32

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:13:38
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:49:38

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:32

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 14:45:01
User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 09:33:27
Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:13:50
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 13:13:38
User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:56:19
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:49:38

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:32

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:32

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:32

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:32

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:32

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered empty.	System	01 Feb 2021 14:48:32

US3672092

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

Form: Unblinding

Generated On: 11 Aug 2021 23:03:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered empty.	System	01 Feb 2021 14:48:32

US3672092

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:46

US3672092

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:46

US3672092

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '14:00'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:46

US3672092

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '29 Jan 2021 14:00'	System	01 Feb 2021 14:48:46

US3672092

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:03:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:59

US3672092

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:03:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:48:59

US3672092

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:03:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '13:12'	(b) (4), (b) (6)	01 Feb 2021 14:48:59

US3672092

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:03:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:29
User entered '29 Jan 2021 13:12'	System	01 Feb 2021 14:48:59

US3672092

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 23:03:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 13:52:13

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Left Arm, Right Arm, etc.) and type (i.e., Urticarial or Non-Urticarial) of REDNESS AT INJECTION SITE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:03:38
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Swelling of injection site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 09:22:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 09:22:37
Query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Left Arm, Right Arm, etc.) and type (i.e., Urticarial or Non-Urticarial) of REDNESS AT INJECTION SITE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.'	(b) (4), (b) (6)	19 Oct 2020 20:31:20
answered with 'updated to clarify which arm was involved in AE' (Site from DM).		
Data point term sent to Coder	System	19 Oct 2020 20:31:12
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 20:30:52
User entered 'SWELLING AT INJECTION SITE (L)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:30:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Swelling of injection site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:29:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:29:26
Data point term sent to Coder	System	19 Oct 2020 20:28:08

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Swelling of injection site - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 20:27:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 20:27:34
Query 'For coding purposes, please split REDNESS AND SWELLING AT INJECTION SITE into separate entries.' canceled (Site from System).	Coder Import (b) (4)	19 Oct 2020 20:27:20
Data point term sent to Coder	System	19 Oct 2020 20:27:04
User entered 'SWELLING AT INJECTION SITE' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:26:31
User opened query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Left Arm, Right Arm, etc.) and type (i.e., Urticarial or Non-Urticarial) of REDNESS AT INJECTION SITE. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:27:45
User opened query 'For coding purposes, please split REDNESS AND SWELLING AT INJECTION SITE into separate entries.' (Site from System).	Coder Import (b) (4)	08 Sep 2020 11:01:39
Data point term sent to Coder	System	01 Sep 2020 13:54:54
User entered 'REDNESS AND SWELLING AT INJECTION SITE'	(b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 13:56:02
User entered 'No (N)' reason for change: Data Entry Error	System	01 Sep 2020 13:56:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 13:56:02
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM). Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'UPDATED' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:09:20
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Oct 2020 22:11:49
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 22:11:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 11:27:55
	(b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per CDM: Response noted. Start Time is Unknown. However, entered time is 00:00 suggests midnight (24 HR clock). Please remove any time data if unknown. Thank you ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:57:59
Query 'Per CDM: Response noted. Start Time is Unknown. However, entered time is 00:00 suggests midnight (24 HR clock). Please remove any time data if unknown. Thank you ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:49:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 14:48:51
User opened query 'Per CDM: Response noted. Start Time is Unknown. However, entered time is 00:00 suggests midnight (24 HR clock). Please remove any time data if unknown. Thank you ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:36:06
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 11:15:08
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'TIME IS UNKNOWN AS PER PATIENT .' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 13:54:37
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Sep 2020 13:54:10
User entered '00:00'	(b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 14:48:51
User entered '21 Aug 2020 00:00'	System	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per CDM: Response noted. End Time is Unknown. However, entered time is 00:00 suggests midnight (24 HR clock). Please remove any time data if unknown. Thank you ' (Site from DM).	(b) (4)	
Query 'Per CDM: Response noted. End Time is Unknown. However, entered time is 00:00 suggests midnight (24 HR clock). Please remove any time data if unknown. Thank you ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:58:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 14:49:29
User opened query 'Per CDM: Response noted. End Time is Unknown. However, entered time is 00:00 suggests midnight (24 HR clock). Please remove any time data if unknown. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:48:51
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 15:36:29
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'TIME IS UNKNOWN AS PER PATIENT.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 11:15:13
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	01 Sep 2020 13:54:46
User entered '00:00'	(b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 14:48:51
User entered '27 Aug 2020 00:00'	System	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 13:56:02
User entered 'Related (RELATED)' reason for change: Data Entry Error	System	01 Sep 2020 13:56:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 13:56:02
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per CDM: Kindly confirm why this is 'Not Applicable and Please update appropriately or else, clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:50:35
Query 'Per CDM: Kindly confirm why this is 'Not Applicable and Please update appropriately or else, clarify. Thank you.' answered with 'Subject not given second injection.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 20:32:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:31:47
User opened query 'Per CDM: Kindly confirm why this is 'Not Applicable and Please update appropriately or else, clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:48:05
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 13:56:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 13:56:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 13:56:02
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 13:54:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:35:06
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 13:59:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 13:59:18
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 13:59:18
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 13:59:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 13:59:03
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 13:56:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 13:56:02
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 13:56:02
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 13:54:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:54:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

None

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	01 Sep 2020 13:57:31
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 13:57:31
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	01 Sep 2020 13:57:18
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Sep 2020 13:56:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 13:56:14
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Sep 2020 13:54:10
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:57:18
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 13:56:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 13:56:02
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 13:54:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:54:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Sep 2020 13:54:10

US3672092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:03:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Sep 2020 13:56:02

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 18:28:25
Query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	06 Nov 2020 19:29:09
' answered with 'unknown' (Site from DM).		
User opened query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 23:58:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 22:55:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 22:55:25
Data point term sent to Coder	System	19 Oct 2020 20:32:13
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 20:31:37
User entered 'REDNESS AT INJECTION SITE (L)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:31:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 20:29:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 20:29:25
Data point term sent to Coder	System	19 Oct 2020 20:28:08
User entered 'Redness at injection site'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events and this is considered as Unsolicited event. Please review and update response to 'Was this a Solicited Adverse Reaction?' was appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:14:33
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events and this is considered as Unsolicited event. Please review and update response to 'Was this a Solicited Adverse Reaction?' was appropriate. Otherwise, clarify.' answered with 'Correction made per query' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:25:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 15:25:03
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events and this is considered as Unsolicited event. Please review and update response to 'Was this a Solicited Adverse Reaction?' was appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 08:01:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '21 Aug 2020'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User entered empty.	System	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	19 Oct 2020 20:28:37
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Oct 2020 20:28:37
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Oct 2020 20:28:06
User entered '27 Aug 2020'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User entered empty.	System	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 20:28:37
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	19 Oct 2020 20:28:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Oct 2020 20:28:06
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:28:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Related (RELATED)'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:28:06

US3672092

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query ' Per CDM: Please consider to complete 'Dosing discontinuation' page appropriately or else provide clarification. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:00:00
Query ' Per CDM: Please consider to complete 'Dosing discontinuation' page appropriately or else provide clarification. Thank you ' answered with 'dosing discontinuation completed' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:13:02
User opened query ' Per CDM: Please consider to complete 'Dosing discontinuation' page appropriately or else provide clarification. Thank you ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:32:09
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:29:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 20:29:01
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:29:01
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:28:06
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:28:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User entered '0'	System	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User entered '1'	System	19 Oct 2020 20:28:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:03:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:13:01
User entered '0'	System	19 Oct 2020 20:28:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:03:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:55
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:07:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
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)	21 Feb 2021 21:07:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Feb 2021 21:07:48
Data point term sent to Coder Coding entries removed.	System Patty Howenstine (b) (4)	15 Feb 2021 18:53:01 15 Feb 2021 18:52:22
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)	05 Nov 2020 04:16:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 04:16:43
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	27 Oct 2020 13:47:14 27 Oct 2020 13:46:25
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)	14 Aug 2020 14:17:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 14:17:18
Data point term sent to Coder	System	14 Aug 2020 14:15:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'IBUPROFEN'	(b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 17:59:31
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'will update' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 20:10:10
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 08:31:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ARTHRITIS (e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:02:26
Query 'Per DM CLR: Please update the indication to reflect the location and type of ARTHRITIS (e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'done' (Site from DM).	Patty Howenstine (b) (4)	15 Feb 2021 18:53:11
User entered 'OSTEOARTHRITIS (joints)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	15 Feb 2021 18:52:31
User entered 'OsteoARTHRITIS' reason for change: Data Entry Error	Patty Howenstine (b) (4)	15 Feb 2021 18:52:22
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ARTHRITIS (e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:53:11
User closed query 'Per CDM Re-Query: Please update here as well. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:17:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM Re-Query: Please update here as well. Thank you' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:46:31
User entered 'JOINT PAIN/Arthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 13:46:25
User opened query 'Per CDM Re-Query: Please update here as well. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:50:52
User closed query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of JOINT PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:50:52
Query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of JOINT PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'listed in medical history' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:12:22
User opened query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of JOINT PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:13:11
User entered 'JOINT PAIN'	(b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '800'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'TWO TIMES WEEKLY'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 21:01:11
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.'	(b) (4), (b) (6)	14 Aug 2020 14:17:29
answered with 'PATIENT IS CURRENTLY ON CON MED.' (Site from System).		
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	14 Aug 2020 14:14:53
User entered 'UN UNK 2014'	(b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:14:53

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
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	14 Aug 2020 14:16:34
User entered 'No (N)' reason for change: Data Entry Error	System	14 Aug 2020 14:16:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:16:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:14:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:14:53

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:14:53

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:03:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:14:53

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 09:29:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 09:29:52
Data point term sent to Coder	System	01 Sep 2020 13:43:27
User entered 'PREDNISONE'	(b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'REDNESS AND SWELLING AT INJECTION SITE.'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '10'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User entered '1'	System	01 Sep 2020 13:43:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User entered '1'	System	01 Sep 2020 13:43:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:03:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:35
User entered '804 (804)'	System	01 Sep 2020 13:43:24

US3672092

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:03:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:36:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:47:47

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:03:53

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
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	23 Oct 2020 13:21:40
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 13:21:40
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 13:10:45
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 13:10:45

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:03:53

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 16:14:43
Query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:37:22
User opened query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:02:48
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	23 Oct 2020 13:10:45

US3672092

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:03:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:53:14
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:51:53
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'OK' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:57:58
User entered 'AE#1, AE #2' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 13:57:51
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:12:56
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 16:14:45
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:38:01
User entered 'AE 1 and AE 2' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:37:57
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:30:20
User entered 'Swelling at injection site'	(b) (4), (b) (6)	23 Oct 2020 13:10:45